

JOURNAL

THE UNITED STATES ARMY
MEDICAL DEPARTMENT



THE MEDICAL-LEGAL PARTNERSHIP IN THE ARMY MEDICAL DEPARTMENT



January - March 2010

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**THE UNITED STATES ARMY
MEDICAL DEPARTMENT**

A Professional Publication
of the AMEDD Community

JOURNAL

Online issues of the *AMEDD Journal* are available at <http://www.cs.amedd.army.mil/dasqaDocuments.aspx?type=1>

January – March 2010

The Army Medical Department Center & School

PB 8-10-1/2/3

LTG Eric B. Schoomaker

*The Surgeon General
Commander, US Army Medical Command*

MG Russell J. Czerw

*Commanding General
US Army Medical Department Center and
School*



By Order of the Secretary of the Army:

Official:

JOYCE E. MORROW
*Administrative Assistant to the
Secretary of the Army*

GEORGE W. CASEY, JR
*General, United States Army
Chief of Staff*

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1006801

The *Army Medical Department Journal* [ISSN 1524-0436] is published quarterly for The Surgeon General by the US Army Medical Department Center & School, ATTN MCCS-HT, 2419 Hood ST STE C, Fort Sam Houston, TX 78234-7584.

CORRESPONDENCE: Manuscripts, photographs, official unit requests to receive copies, and unit address changes or deletions should be sent to the *Journal* at the above address. Telephone: (210) 221-6301, DSN 471-6301

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Perspective

Major General Russell J. Czerw



MEDLINE Selects The *AMEDD Journal*

It is indeed my pleasure to announce that the *Army Medical Department Journal* has been selected to be included and indexed in MEDLINE, the National Library of Medicine's bibliographic database of life sciences and biomedical information. As such, articles published in the *AMEDD Journal* are now indexed and available to researchers and writers through the PubMed search interface. The *AMEDD Journal* joins the ranks of the world's finest medical science periodicals in the database, ensuring that the contributions of our dedicated military medical professionals are readily accessible throughout the global scientific and academic communities. This selection is the culmination of several years of work to elevate the *AMEDD Journal* to the standards of the National Library of Medicine, and is a major milestone in the continuing efforts to ensure only the highest quality of content is presented within Army medicine's premier publication. I strongly encourage all medical professionals, military and civilian, to take advantage of this exciting opportunity to share results, observations, opinions, and ideas which have application or perspectives in military medical science.

In the mythical ideal world, the practice of medicine would always be a straightforward proposition. The skilled practitioner applies the knowledge, experience, and insights gained from years of education and dedicated practice to address the patient's problems. The patient, in turn, understands and accepts the limitations, complexities, and risks associated with medical treatment, and makes every effort to cooperate and assist the healthcare provider in his or her care. Both the caregiver and patient benefit, the former obtaining more experience and knowledge with which to pursue the practice, and the latter satisfied with the outcome. Of course that ideal world scenario presupposes that work within medical science and the practice of medicine are undertakings free from external complications and constraints.

Unfortunately, the reality is that medical professionals, both civilian and military, pursue their occupations in an extraordinarily complex, intensely

regulated, and highly litigious world. No area of medicine is immune, certainly not the healthcare providers, but also those in research, manufacturing, pharmacology, training, logistics, and even those who are responsible for the facilities that house the various functions of modern medical practice—and that list is far from complete. Such concerns and external factors severely complicate the application of the actual medical skills and training that practitioners have dedicated years to perfect, and too often are distractions to their work.

Fortunately for those of us who work as Army medical professionals, there are specialized legal professionals of the Army Judge Advocate General (JAG) Corps who are our partners in navigating the labyrinth of overlapping, interlocking, and often obscure laws, regulations, rules, protocols, procedures, and restrictions that are involved in work in the medical sciences. They are an invaluable resource that is absolutely necessary for us to do what we should do best, care for the health and well-being of our Soldiers, their families, and our military retiree community. The attorneys, paralegals, and administrative personnel are actively involved, both directly and behind the scenes, in decision processes, planning, and drafting and publishing all manner of procedures, protocols, directives, and guidelines. Additionally, they provide consult on the myriad of issues that are encountered at literally every level of the Army Medical Department every single day. It is not exaggeration to say that the delivery of healthcare would be almost impossible without their involvement as our advisers, advocates, and sometimes defenders—truly our partners in our chosen professions.

MAJ Joseph Topinka, the Deputy Staff Judge Advocate for the Army Medical Command at Fort

Perspective

Sam Houston, has assembled a collection of articles from the JAG community within Army medicine. These 12 articles touch some of the more important and often-encountered legal subjects in military medicine. The articles address concerns of patients, those of the institutions (medical commands, hospitals, clinics, research activities, etc), and topics of direct interest to healthcare providers. However, as diverse and complete as these articles are, they represent only a fraction of the many areas in which Army medicine relies on the knowledge and experience of the Army JAG Corps.

As the level of capabilities and sophistication of medical science has markedly increased over the years, so has the ability of military medicine to save the lives of our wounded Warriors on the battlefield. Many more of the wounded survive their injuries than ever before in history, but sometimes with the prospect of living with a disability for the rest of their lives. Of course the military provides extensive rehabilitative care and resources, but many of those Warriors' injuries render them unfit for continued military service. Mr Duke Dorotheo's detailed, comprehensive article addresses the processes and participants in the various stages that the disabled Soldier may experience in the determination of his or her discharge from active duty, or, in some cases, retention in active status. This article gives great insight into the complexity of the structure that exists to comply with the Department of Defense and Army instructions, regulations, and directives, which themselves are necessary to implement the federal laws governing disabled military personnel. Mr Dorotheo provides a wealth of information useable by everyone with an interest in the process, including injured Soldiers themselves.

Peer review is usually thought of in the context of the evaluation of an individual's capabilities, conduct, or other aspects of professional qualifications. However, Army medicine employs peer review in an important role in risk management at medical treatment facilities and hospitals. Risk management peer review is actuated by an event that occurs during patient care that results in injury, the filing of a medical claim, or notification of payment of a claim settlement or award. It is an essential part of the inquiry into the facts and circumstances involved in the incident in question. LTC Anthony Kutsch's article clearly presents a description of the processes, the underlying regulations and federal statutes, and the various possible

outcomes. The article provides a detailed discussion about this extremely important component of the Army Medical Department's robust quality control structure, which itself is an essential element in maintaining the high level of care that our Soldiers and other eligible patient populations deserve every day.

Karin Zucker and her coauthors have contributed an article which explores a topic that, on the surface, seems simple, but in reality is a potentially complicated element of patient care with serious legal implications. Today, a patient's consent is an obvious requirement before a healthcare provider may begin treatment, whether a simple action, a surgical procedure, or a complex, long-term course of treatments, perhaps involving extended discomfort or actual risk. However, it has not always been that way. As detailed in the article, today's concept of informed consent has actually evolved over the years through a series of legal decisions. Although most people may think that they intuitively understand what it means to give consent to medical treatment, from a legal perspective nothing could be further from the truth. This article expands the concept into its elements and subelements to provide an understanding of the importance of addressing the smallest details of judging the patient's capability to understand information, presenting the details of the treatment such that the patient can make an informed decision, and ensuring that decision is completely voluntary (free from coercion or overt influence). This is an eye-opening look at just one of the basic parts of healthcare delivery in which legal expertise is absolutely vital.

At the other end of the treatment decision spectrum are the physician's decisions as to whether to begin treatment, or to end treatment already underway, notwithstanding the desires of the patient or those legally responsible for the patient. This area involves the concept of medical futility. As Mark Sposato defines it in his article, "medical futility generally refers to interventions that are unlikely to produce any significant benefit for the patient." Although several states have attempted to address this difficult decision area through statutes, the experience of healthcare providers continues to demonstrate that attempts to legislatively stipulate items within an area of so many conjectural, even hypothetical components are usually insufficient, and often complicate the predicament even further. Mr Sposato's excellent article contains a number of examples and case studies demonstrating the twists and turns in such decision situations, and the

complications that arise as conflicting interests and legal actions become involved. Further, he discusses some of the various statutory efforts to address medical futility, and explains both their strong points and shortcomings. This is a comprehensive, very informative overview of this difficult subject, and is a “must-read” for healthcare practitioners who could potentially face such decisions.

Medical research makes extensive use of computer models, laboratory experiments, and animal studies, but at some point human subjects must be involved to validate everything that has been learned through the other techniques. Unfortunately, human history contains far too many horrific examples of human experimentation that was not bound by any moral or ethical concerns, and was conducted on imprisoned subjects without regard to their welfare, sometimes with government sponsorship. Stephen Maleson’s article is a comprehensive, well researched discussion of the evolution of this very sensitive topic which bridges statutes, regulations, international agreements and protocols, and, perhaps most important, ethics. Similar to the parameters surrounding informed consent to treatment, the overriding principle that has been championed in international codes and declarations, various national protocols and guidelines, and codified into national laws is that researchers must have the voluntary, informed consent of a prospective subject or a subject’s legal representative before any experimentation may begin. Mr Maleson develops the topic from the historical, global perspective and moves into the details of the rules and regulations that apply for involvement of human subjects in research by US companies and agencies, specifically that conducted by Department of Defense and Army researchers. This article is replete with important information and details, and should be a valuable reference source for those considering or developing a research project that will ultimately involve human subjects.

As we all know, military personnel, retirees, and their dependents are eligible for treatment at military medical treatment facilities, no matter the cause for the condition requiring treatment. However, not so well-known is that the military may seek reimbursement for the costs of treatment which is necessitated by action of a third party (not associated with the federal government). Further, the government may also seek reimbursement of the wage costs for those service members unable to perform their duties due to injury by a nonfederal source. In her excellent article,

Melissa Hartley describes one structure for recovery, the Medical Affirmative Claims Program, in detail, including the authorizing laws, regulations, and directives, and the various situations and conditions that apply in the process. The recovery may be from several avenues, depending on the circumstances involved in the patient’s condition. The effort required in the reimbursement recovery process is directly compensated in that the bulk of the recovered funds are retained by the facility where the care was rendered. The information in this article should be carefully reviewed at military medical treatment facilities and hospitals to ensure that the Medical Affirmative Claims Program is used to the maximum extent to recover every cost to which the facility may be entitled.

One of the unfortunate realities of any profession is that, despite sophisticated accreditation and certification requirements, there will be practitioners of the profession who are not completely competent in their chosen field, for any number of reasons. The practice of medicine, including that within the military, is not immune to this problem. Rosalind Gagliano has contributed an important article that details the process by which the military monitors the competence of its practitioners, and the actions that are available to address suspected problems. A healthcare practitioner is granted clinical privileges to practice in a military medical treatment facility by the credentials committee, under the authority of the facility commander. Actions taken to limit or remove those privileges are called adverse privileging actions, and are a serious step which can sometimes mean the end of a career. For this reason, a considerable statutory and regulatory structure governs the system by which adverse privileging actions are initiated, processed, and reported. The legal and practical implications of any such actions are considerable, and close involvement of specialized legal professionals in the process is a must. Ms Gagliano lays out the history of the existing structure from the original federal legislation in 1986, and describes the military implementation of those requirements with Department of Defense and Army regulations. This article is a carefully constructed, clearly written, specifically referenced discussion of this extremely important aspect of quality assurance in the Army Medical Department. The health and safety of our Soldiers and all other patients in the military medical system depend upon unwavering attention to any indication of less than the best from our healthcare providers.

Perspective

The creativity, initiative, and spirit of innovation that exists throughout Army medicine are invaluable assets for maintaining the extremely high level of healthcare service that is provided to our Warriors throughout the world. Our professionals are constantly seeking ways to do it better, faster, and more efficiently, no matter what “it” may be. A search for improvement may result in a device, a book, or a software package that is applicable in both military and civilian environments. Such things are originally ideas, and are now recognized as important legal entities called intellectual property, with the same possible economic value as the physical inventions with which we are familiar. Army medicine formally pursues a considerable amount of research, representing a significant amount of value in intellectual property, all of which must be protected. Elizabeth Arwine and Jill Caldwell have written a very interesting and informative article that provides an overview of the many federal laws and agency regulations that govern the legalities involved in creating and protecting inventions in the course of federal employment, to include intellectual property. As they define and describe the various protections established by law, they also carefully frame the relationship of those protections to those of us who may conceive or create a useful item or idea as part of our job. Also, there are provisions for sharing in any royalties that the government may receive for one’s invention. This article is a primer for those who may be interested in developing an idea or device to improve their work efficiency or effectiveness.

MAJ Joseph Topinka opens his article with the following: “Medical personnel in the US military are extensively educated, trained, and experienced professionals whose expertise is in high demand.” With that sentence, he defines the essence of the high quality level of military medicine that exists today, but he also sets the framework for potentially serious problems for those highly skilled medical practitioners. The “high demand” that exists for those individuals comes from numerous private sources: professional organizations, private companies, universities, hospitals, etc. Such entities are more than willing to fund the travel costs of those invited to various forums to share their expertise. Therein lies the potential for problems. Federal government employees may only accept travel benefits within a rigid framework strictly defined by several statutes and

regulations. MAJ Topinka’s article is an excellent, comprehensive presentation of the various situations and conditions that dictate whether or not travel benefits may be accepted, and the approval processes for the types of travel that are allowed. This article should be made available as an easy to understand resource for those who may receive inquiries or invitations from outside organizations.

The same professional expertise and capabilities that create the demand for military medical professionals at conferences and seminars also make them highly employable while off-duty. Employers recognize that a military healthcare provider represents the entire “package” of education, training, experience, skill, and discipline, an unquestionable value. The military does not prohibit such employment in most cases, but there are specific limitations and conditions that apply to these arrangements. CPT Holly Bryant’s article discusses the regulations and policies that govern off-duty employment of military healthcare providers. The article categorizes the types of employment of concern, addresses the limitations of such employment, and outlines the procedures to obtain approval from the provider’s commander. The rules and requirements are specific and detailed, but are necessary to ensure that the potential off-duty employment will have no effect on the provider’s primary obligation—the health and well-being of the American Warrior.

Another demand for military healthcare practitioners comes directly from the legal community. Providers are often sought as witnesses in litigation, but their participation in such a venue is conditional and highly regulated. CPT Ean White has provided a succinct, clear discussion of the types of litigation, the limitations of provider participation, and the approvals that must be obtained before an individual may participate. His article makes it very clear that a healthcare provider should immediately contact the military legal counsel serving the facility as soon as he or she is notified of the request to be a witness. Even if the circumstances seem straightforward and innocuous, unrecognized factors may make participation risky for the individual, both professionally and personally. The military legal counsel is there to ensure that neither the provider nor the military are placed in a position of embarrassment or financial risk.

The Army Physical Disability Evaluation System

Lakandula Duke Dorotheo, JD

PURPOSE

This article provides a working knowledge of the Army's Physical Disability Evaluation System (APDES) and discusses changes in the APDES mandated by the National Defense Authorization Act for Fiscal Year 2008¹ and disability-related provisions of the National Defense Authorization Act for Fiscal Year 2009.²

OVERVIEW

Chapter 61, 10 USC provides the Secretaries of the military departments of the United States with authority to retire or discharge a member if they find the member unfit to perform military duties because of physical disability. The US Army Physical Disability Agency (PDA), under the operational control of the Commander, Human Resources Command, is responsible for operating the Physical Disability Evaluation System (PDES) and executes Secretary of the Army decision-making authority as directed by Congress in Chapter 61, 10 USC. *Department of Defense Directive 1332.18*,³ *Department of Defense Instruction 1332.38*,⁴ *Army Regulation 40-400*,⁵ *Army Regulation 40-501*,⁶ *Army Regulation 635-40*,⁷ and *Army Regulation 600-60*⁸ set forth the policies and procedures implementing the statute. The PDA is currently located at the Walter Reed Army Medical Center, Washington, DC.

As delineated by *Army Regulation 635-40*, the objectives of the APDES are to maintain an effective and fit military organization with maximum use of available manpower; provide benefits for eligible Soldiers whose military service is terminated because of service connected disability; and provide prompt disability processing while ensuring that the rights and interests of the government and the Soldier are protected.^{7(p1)}

REFERRAL INTO THE PHYSICAL DISABILITY EVALUATION SYSTEM

The Joint Department of Defense (DoD) and Department of Veterans Affairs Disability Evaluation

System Pilot Project involves a different process and is discussed later in this article. The next several sections will focus on the "legacy" disability evaluation system. In the legacy system, Soldiers can be referred into the APDES in 1 of 5 ways:

- Medical Evaluation Board (MEB)
- Military Occupational Specialty/Medical Retention Board
- Command Directed Fitness Determination
- Department of the Army Directed Fitness Determination
- Reserve Component Nonduty-Related Fitness Determination

Medical Evaluation Board

The medical treatment facility initiates a MEB when a Soldier has reached "Optimum Hospital and Medical Treatment Benefit" and has a P3 or P4 permanent medical profile (see discussion on page 6).⁹ The MEB determines if, under the provisions* of chapter 3, *Army Regulation 40-501*,^{6(pp20-38)} the Soldier meets Army retention standards for each of his or her medical conditions.

The MEB will issue a Medical Evaluation Board Proceedings report on Department of the Army (DA) Form 3947 which itemizes each medical condition and states whether they meet or do not meet Army retention standards. If all medical conditions on the DA Form 3947 meet retention standards, the Soldier is returned to duty or referred for Military Occupational Specialty (MOS)/Medical Retention Board processing for possible MOS reclassification. If at least one condition does not meet medical retention standards, then the Soldier is referred to the Physical Evaluation Board (PEB) to determine if he or she is fit for duty.

Please note that even though the MEB will make preliminary findings for each condition whether they

*Chapter 3 of *Army Regulation 40-501* provides objective criteria to determine the standards for medical retention for a number of medical conditions.

The Army Physical Disability Evaluation System

were service incurred, existed prior to service, or if there was any service aggravation, under *Army Regulation 635-40*,^{7(pp96-98)} the ultimate decision whether a condition is compensable is reserved for the PEB.⁹ Additionally, under *Army Regulation 635-40*, the ultimate decision of a Soldier's fitness is the province of the PEB and PDA. A Soldier is not automatically unfit because of a failure to meet Army retention standards.

Practice Points for Medical Evaluation Boards

Report of Medical Evaluation Board Proceedings (DA Form 3947). All Soldiers are encouraged to consult with an MEB outreach counsel or Soldiers counsel upon receipt of their DA Form 3947 and supporting documentation. All medical conditions, regardless of severity, should be listed on the DA Form 3947 and analyzed by the MEB.^{7(pp3,96)} Normally, the PEB can only determine if a medical condition is "unfitting" (preventing the Soldier from performing PMOS duties and/or basic soldiering skills) if they are listed on the form as "medically unacceptable" under *Army Regulation 40-501*.⁶ While the PEB has the authority to find any medical condition unfitting, they normally only consider those medical conditions which have been vetted through the MEB process as "medically unacceptable" in accordance with chapter 3, *Army Regulation 40-501*.^{6(pp20-38)} If the Soldier disagrees with the MEB, he or she may appeal by indicating their nonconcurrence on the DA Form 3947 itself and submitting a written statement. The Deputy Commander of Clinical Services (DCCS) is obligated to consider the Soldier's appeal and indicate what action has been taken, including confirmation of the original MEB findings. The DCCS is the designated authority for the MEB process. If a condition is missing or if a new condition which could likely be medically unacceptable arises after referral to the PEB, the Soldiers counsel or MEB outreach counsel should insist on having the case pulled back by the MEB or returned by the PEB.

Physical Profile. When the Soldier is seeking disability retirement, it is extremely important that block 1 of the physical profile (DA Form 3349) lists all of the medically unacceptable conditions as found in the MEB report (DA Form 3947). In some cases the PEB has determined that a medical condition is not unfitting

just because it was not addressed in the profile as limiting the Soldier's abilities, even if it was addressed in the narrative summary and DA Form 3947 as medically unacceptable. Obviously, for a Soldier who is seeking a finding of fit, it is better to have fewer medical conditions listed in block 1.

If the Soldier is seeking a finding of unfit, it is crucial that a permanent 3 (P3) or higher rating is assigned in the appropriate PULHES (see inset) category for the corresponding medical condition on his or her physical profile DA Form 3349 (top right corner).^{6(pp73-83)} Each PULHES criteria is assigned a number from 1 to 4 indicating the level of restriction. Further, each restriction is categorized as temporary or permanent. Level 1 indicates a high level of medical fitness, and level 2 indicates some medical condition or physical defect that may require some activity limitations but not so severe as to make fitness for duty questionable (it is important to note that P1 and P2 conditions are not considered unfitting by the PEB). Level 3 indicates one or more medical conditions or physical defects which may require significant duty restrictions or assignment limitations. Level 4 indicates one or more medical conditions or physical defects of such severity that performance of military duty must be drastically limited.

| PULHES |
|----------------------------------|
| P - Physical capacity or stamina |
| U - Upper extremities |
| L - Lower extremities |
| H - Hearing and ears |
| E - Eyes |
| S - Psychiatric |

Independent Physician Review. Section 1612(a)(2)(D) of the National Defense Authorization Act for Fiscal Year 2008¹ provides Soldiers, upon request, a physician who is independent of the MEB to review the

MEB records and provide counsel on the findings and recommendations.¹⁰ Further, the independent physician advises the Soldier on whether the findings of the MEB adequately reflect the complete spectrum of his or her injuries and illness. After review of findings with the assigned impartial health care professional, the Soldier shall be afforded an opportunity to request a rebuttal of the earlier MEB results. The Soldier, upon receipt of the independent medical review report, shall be afforded 7 calendar days to prepare a rebuttal, if appropriate, to the convening medical authority.

Optimum Medical Treatment Benefit v "One Year Rule." *Department of Defense Instruction 1332.38* defines "optimum hospital and medical treatment benefits" as the point of hospitalization or treatment when a

member's progress appears to be stabilized, or when, following administration of essential initial medical treatment, a determination can be made of the patient's medical prognosis for capability of performing further duty.^{4(p8)} Also, under the changes to *Department of Defense Instruction 1332.38* mandated by the Under Secretary of Defense for Personnel and Readiness on October 14, 2008,^{10(p3)} referrals for MEB processing will occur within one year of a diagnosis of a medical condition(s) that does not appear to meet medical retention standards. However, a referral may be earlier if the examiner determines that the member will not be capable of returning to duty within one year. The 2 provisions sometimes conflict with each other. We have seen Soldiers referred into the Physical Disability Evaluation System even though they have not yet reached Optimum Hospital and Medical Treatment Benefit, due to the sole fact that they have been in a Warrior Transition Unit for more than a year. In those instances, we attempt to contact the medical treatment facility (MTF) to have the case pulled back or ask the PDA to return the case to the MTF. A clear case of lacking Optimum Hospital and Medical Treatment Benefit is the scheduling, after the Soldier's referral to the PEB, of surgery which has the potential to keep him or her on active duty.

Military Occupational Specialty/Medical Retention Board

A Soldier cannot reclassify his or her MOS at an MEB or PEB. Military Occupational Specialty/Medical Retention Boards (MMRBs) are not part of the APDES, they are part of the US Army's Physical Performance Evaluation System and operate under *Army Regulation 600-60*. That regulation stipulates that MMRBs only evaluate Soldiers who have been issued a permanent physical profile with a P3 or P4 and whose medical conditions are medically acceptable.^{8(ppi,2-4)} An MMRB referral is made by the Soldier's servicing MTF when those conditions are met. The MMRB determines if a Soldier has the physical ability to satisfactorily perform their PMOS (primary military occupational specialty) or branch duties worldwide and in a field environment. The MMRB may take one of 4 actions when reviewing a case: a direct referral to an MEB/PEB, retain in PMOS/Branch, trial of Duty/Probationary status, or reclassification. To be recommended for retention, probation, or reclassification, Soldiers at a minimum must be able to perform the following common tasks:

fire individual weapon; wear the ballistic helmet, load-carrying equipment and protective mask; and perform one of the alternate aerobic events of the Army physical fitness test when the profile precludes the standard 2-mile run. If a Soldier cannot be retained in his or her PMOS or reclassified to another, they will be referred to the PEB to determine fitness for duty. The PEB is not bound to find MMRB-referred Soldiers unfit. If the MMRB refers a Soldier to the MEB, the MEB cannot directly return the Soldier to duty unless the physical profile is changed by the MTF to a P2 or lower. MEB outreach counsel and Soldiers counsel do not participate in MMRB proceedings, however, they can counsel Soldiers going through the process. Under *Army Regulation 600-60*, Soldiers are not entitled to legal counsel at MMRB proceedings.^{8(p11)}

Command Directed Fitness for Duty Examination

Pursuant to paragraph 5-4.c.(7)(c) of *Army Regulation 600-20*,^{11(p37)} commanders may direct a medical examination at an MTF to determine a Soldier's fitness for duty. This occurs when a commander questions the Soldier's ability to perform his or her PMOS or branch duties due to a medical condition. The Soldier may or may not be under temporary or permanent profile. This examination may cause referral to the PEB if the findings show that the Soldier's condition falls below Army retention standards.

Headquarters, Department of the Army Directed Fitness Determination

The Commander, Human Resources Command (HRC), upon recommendation of the Office of The Surgeon General, may also direct an MTF medical examination to determine a Soldier's fitness for duty. The Commander, HRC, may also disapprove the MMRB's recommendation to reclassify a Soldier's PMOS and directly refer the Soldier into the MEB or PEB.

Reserve Component Nonduty-Related Fitness Determination

Department of Defense Directive 1332.18^{3(p3)} and *Department of Defense Instruction 1332.38*^{4(p27)} address Reserve Component (RC) members pending separation for failure to meet medical retention standards completely due to medical impairments incurred outside of military service and involve no issue of aggravation while in a duty status.¹² Such cases usually arise when a Soldier is mobilized and

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cannot deploy pursuant to a Soldier readiness processing medical examination. They also arise when RC members undergo their mandatory 5-year examination. If the PEB determines that the RC member is unfit, he or she is separated without entitlement to benefits. The PEB hearing is to solely determine fitness, not compensability.

Practice Point for Nonduty-Related Fitness Determinations

In nonduty-related fitness determination cases, Soldiers do not undergo MEB processing (a duty-related process). Accordingly, the evidence file will include neither a DA Form 3947, narrative summary, nor an addendum. In these types of cases, the PEB can only determine fitness, as compensation is not an issue. However, if the PEB discovers evidence that the medical conditions for which the RC Soldier was referred for nonduty adjudication may be service-incurred or service-aggravated, they must return the case to the Soldier's RC command to evaluate the new evidence for possible referral into the duty-related MEB process. Reviewing the RC member's civilian medical records is extremely important, especially if the treatment notes establish a service-connected medical condition or show no degree of restriction if the Soldier wants to be found fit for duty. Obtaining civilian job performance data from the Reservist's civilian supervisors and letters supporting retention from their military chain of command may also help support a fit for duty finding.

THE PHYSICAL EVALUATION BOARD

If a Soldier has a P3 or P4 profile and the MEB determines that he or she has at least one medically unacceptable condition, the case is forwarded to the PEB for adjudication. There are 3 PEB sites: Walter Reed Army Medical Center, Washington, DC; Brooke Army Medical Center, Fort Sam Houston, Texas; and Madigan Army Medical Center, Fort Lewis, Washington. The PEBs issue both informal and formal determinations. If a Soldier disagrees with a PEB's informal determination, the Soldier can request a formal hearing with the assistance of appointed legal counsel. Soldiers may opt to have their own counsel of choice without expense to the Department of the Army. In addition, many veterans service organizations, such as the Disabled American Veterans, American Legion,

and Paralyzed Veterans of America, offer free nonattorney representation to Warriors in Transition.

Presiding Physical Evaluation Board Membership

The PEB will empanel 3 members to make a determination in each case: Presiding Officer, Personal Management Officer, and Medical Member. The Presiding Officer and Personnel Management Officer for the panel will be either a DA civilian adjudication officer assigned to the PEB, or a field-grade officer of any component and of any branch, except the Army Medical Corps (MC). The medical member for the panel will be an MC officer or Army civilian physician, preferably with uniformed service MC experience. The medical member must not have served in any capacity as the Soldier's physician or as a member of the Soldier's MEB. If the case involves an RC Soldier, at least one of the PEB presiding members must be an RC member.^{7(p13)}

Minority, Female, or Enlisted Board Members

A Soldier may request that the presiding board include either enlisted, female, or minority members of the same minority group. For enlisted membership, if available, the enlisted PEB voting member will be ranked sergeant first class to sergeant major, and senior to the Soldier being evaluated. When enlisted PEB membership is provided, the PEB will increase to 5 members, all of whom will have a vote. The fifth member may be enlisted or officer. Requests to include female, minority, or enlisted PEB membership must be in writing and will be granted where reasonably available. The board's determination must include a statement of the Soldier's request, and whether the request for PEB membership was or was not granted.

Physical Evaluation Board Evaluation Process

The PEB determines 4 issues:

- Is the Soldier fit for duty?
- If the Soldier is unfit, are the Soldier's unfitting injuries/conditions compensable?
- If the Soldier is compensable, what level of compensation (rating) will he or she receive?
- Are any of the soldier's unfitting conditions combat-related or caused by an instrumentality of war?

For RC nonduty-related cases (which do not undergo MEB processing), the PEB will only make a determination of fit or unfit. As stated earlier, nonduty-related cases involve impairments incurred completely outside of military service and involve no issue of aggravation while in a duty status. In all cases, the PEB will issue an informal determination and, if requested, a formal hearing with personal appearance with appointed military counsel or counsel of choice.

FIT OR UNFIT FOR DUTY

The mere fact that a Soldier has impairments that fall below Army medical retention standards or appear in the Veterans Affairs Schedule for Rating Disabilities¹³ does not automatically result in an unfit finding. The PEB makes a fitness determination based upon the Soldier's performance data, such as evaluation reports, Army physical fitness test results, and awards. The PEB must make a determination in each case whether the Soldier is reasonably capable of accomplishing both basic soldiering skills and those tasks specific to his or her PMOS, skill level, branch, or specialty duties. *DA Pamphlet 611-21*¹⁴ provides the physical requirements and minimum PULHES scores for each MOS and branch specialty. The PEB will take into account a Soldier's ability to execute basic soldiering skills, such as firing/carrying an M-16, road marching for 2 miles with a full battle load, wearing chemical defense equipment, performing 3-5 second rushes, and constructing an individual firing position. Another factor the PEB will consider includes the Soldier's ability to take an Army physical fitness test, both standard and alternative aerobic events. Soldiers should be able to participate in at least one aerobic event (standard or alternate). The PEB shall take into account all medical conditions, whether individually or in combination, that render the Soldier unfit to perform the duties of their office, grade, rank, or rating.

It should be noted that under a Directive-Type Memorandum revising *Department of Defense Instruction 1332.38* signed on December 29, 2007, by David Chu, Under Secretary of Defense for Personnel and Readiness, the military departments can now consider deployability as a sole consideration when evaluating if a service member is fit or unfit for continued duty. This means that a Soldier who can otherwise perform their assigned duties, but who is nondeployable, can be found unfit. However, please note that at the time of this writing, the Assistant Secretary of the

Army for Military and Reserve Affairs has yet to staff the memorandum for application in the Army.

Strategies for Soldiers Seeking Fit For Duty Determination

A Soldier in the MEB/PEB process who wants to be found fit and returned to duty can benefit from gathering useful evidence for the PEB. Soldiers should gather the following to show that they are fit:

1. Physical profile (DA Form 3349), with as few physical restrictions as possible. Soldiers should review a copy of their most recent physical profile with their chain of command and their treating physician. If the Soldier believes that the profile is too restrictive, he or she should request the physician to make it less restrictive, if appropriate. If the doctor will not provide a less restrictive profile, the Soldier's unit commander has the authority to write in block 20 of the profile that "physical condition does not prevent the Soldier from performing assigned and PMOS duties."

2. A commander's statement supporting a finding of fit. The Soldier should discuss his or her desire to be found fit with his or her chain of command. Many times, unit commanders presume that an injured Soldier wants to be found unfit, and the commander's statement reflects this belief. The Soldier who wants to be found fit should also execute as many PMOS duties and basic soldiering skills as possible to show the chain of command that he or she is fit for duty. A commander's statement indicating that the Soldier has been regularly performing military duties, despite a physical condition, is generally very helpful for a finding of fit.

3. A scorecard indicating that the Soldier recently passed the Army physical fitness test. The Soldier who wants to be found fit should take and pass the Army physical fitness test (APFT) in order to showcase his or her capabilities if the physical profile allows him or her to do so. If the physical profile restricts the Soldier from taking the APFT, the Soldier should obtain the approval of the chain of command prior to violating the profile. The APFT should be conducted to standard under the supervision of the Soldier's chain of command. The APFT card should be completed and signed by the Soldier's training NCO,^a NCOIC,^b 1SG,^c or unit commander.

a. Noncommissioned officer
 b. Noncommissioned officer in charge
 c. 1st sergeant

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4. Noncommissioned Officer Evaluation Reports (NCOERs) and Officer Evaluation Reports (OERs). The Soldier should provide the Board with recent OERs or NCOERs, especially if the evaluations indicate that the Soldier continues to perform military duties despite his or her physical condition.

5. Letters to the PEB from the Soldier's military supervisors stating that the Soldier can perform PMOS duties, Basic Soldier Skills, and pass an APFT. These statements should also address the Soldier's motivation, duty performance, and potential. Photos of the Soldier performing these duties are effective tools for supplementing written statements.

6. Letters to the PEB from the Soldier's supervisor at his or her civilian job. Service members on the Temporary Disabled Retired List, or Soldiers with nonduty-related fitness cases who want to be found fit should submit letters from their current or recent employers stating that their duty performance is not limited by their physical condition. This is especially helpful when the Soldier's civilian occupation is similar to his or her military occupation.

7. Letters to the PEB from physicians stating that the Soldier can perform military duties despite a condition. The Soldier's treating physician may believe that the Soldier can perform military duties despite a physical condition, even if the MEB narrative summary and DA Form 3947 say the Soldier cannot. If so, the Soldier should obtain a note from his or her doctor providing that opinion and the reasons supporting it. The Soldier should also look to other health care providers as well. Physical therapists, chiropractors, counselors, and others who have been working with the Soldier for a long time may know the Soldier's condition very well and may provide valuable information to the Board.

8. Letters to the PEB from people who share physically demanding activities or intellectually challenging hobbies with the Soldier. Soldiers should gather letters from friends who perform with the Soldier in the church choir, the office softball team, or the friendly bowling league, for example, specifying that the Soldier is involved in physically demanding activities or intellectually challenging hobbies. Such statements may provide support that the service member can perform assigned military duties.

General, Flag, and Medical Officers

Paragraph E3.P3.4.2. of *Department of Defense Instruction 1332.38*, states:

An officer in pay grade 0-7 or higher or a medical officer in any grade shall not be determined unfit because of physical disability if the member can be expected to perform satisfactorily in an assignment appropriate to his or her grade, qualifications, and experience. Thus, the inability to perform specialized duties or the fact the member has a condition which is cause for referral to a PEB is not justification for a finding of unfitness.^{4(p27)}

For example, a surgeon who no longer has a steady nondominant hand due to left-hand carpal tunnel syndrome can still perform family medicine or a teaching function.

Presumption of Fitness

The disability evaluation system compensates disabilities when they cause or contribute to career termination prior to retirement. Continued performance of duty until a Soldier is approved for length of service retirement creates a rebuttable presumption that a Soldier's medical condition has not caused career termination. Paragraph E3.P3.5.1. of *Department of Defense Instruction 1332.38* states:

Service members who are pending retirement at the time they are referred for physical disability evaluation enter the disability evaluation system under a rebuttable presumption that they are physically fit.^{4(p27)}

A rebuttable presumption of fitness will apply in a Soldier's case if the dictation of the narrative summary occurs after one of the following instances:

- Soldier's request for retirement is approved
- Selection of officer for selective early retirement was approved
- Officer is within 12 months of mandatory retirement due to age or length of service
- Enlisted Soldier is within 12 months of retention control point and will be retirement eligible at that point.

Rebuttal of the Presumption of Fitness

The presumption of fitness rule shall be overcome when any of the following situations occur:^{4(pp27-28)}

- Within the presumptive period a new acute, grave illness or injury occurs that would prevent the member from performing further duty if he or she were not retiring.
- Within the presumptive period a serious deterioration of a previously diagnosed condition, to include a chronic condition, occurs and the deterioration would preclude further duty if the member were not retiring.
- The condition for which the member is referred is a chronic condition and the preponderance of evidence firmly establishes that the member was not performing duties befitting of either his or her experience in the office, grade, rank, or rating before entering the presumptive period.

PHYSICAL EVALUATION BOARD LIAISON OFFICERS

The Physical Evaluation Board Liaison Officers (PEBLOs) are the administrative liaisons between Warriors in Transition* and the MEB/PEB processes. The PEBLO works under the patient administration division at each medical treatment facility. Despite their name, PEBLOs are US Army Medical Command personnel and are neither PEB nor PDA assets. They are not attorneys, however, they counsel Soldiers undergoing physical disability processing. PEBLOs also serve as the point of contact between Soldiers and MEB members, the Deputy Commander of Clinical Services (DCCS), PEB members, and the PDA adjudicators. PEBLOs collect and prepare Soldiers' MEB packets for presentation to the PEB. A Soldier's MEB packet consists of medical and nonmedical evidence, both administrative and performance data, to assist PEB members in the adjudication of their case.

PEBLOs are available to provide counseling to Warriors in Transition from the time they are referred for MEB processing through the time they are separated from military service. PEBLOs will work with Soldiers counsel, primary care physicians, PEB members, and nurse case managers to obtain required documentation and other medical information.

COMPENSABILITY

Generally, a condition is compensable when it was either incurred in the line of duty or permanently

aggravated by military service. Factors affecting compensability include conditions existing prior to service, misconduct, noncompliance with prescribed medical treatment, and conditions not constituting a physical disability.

Condition Existing Prior to Service

All Soldiers on active duty orders more than 30 days with at least 8 years of equivalent active duty service will overcome any finding that a current medical condition was not caused nor aggravated by the Army and is solely the result of the natural progression of a condition that existed prior to service (EPTS).^{4(p32)} Unless a medical condition is noted at the time of entry, all Soldiers have the presumption of soundness upon entry into military service.^{4(p32)} Stated another way, all conditions are presumed to originate while on active duty. Even when it can be shown that a medical condition did exist prior to military service, all EPTS conditions are presumed service-aggravated. The presumption of soundness upon entry into military service and the presumption of service aggravation are rebuttable presumptions. Both National Defense Authorization Acts 08¹ and 09² modified the compensability rules regarding EPTS conditions and elevated the PEB's evidentiary burden of proof necessary to rebut both presumptions and deny compensation. In order to deny compensation due to EPTS without service aggravation, the PEB must show by "clear and unmistakable evidence" that both the disability existed before the member's entrance on active duty and the disability was not aggravated by active military service.^{10(p6)}

Misconduct

The PEB may also determine that a condition is noncompensable if the injury was caused by the Soldier's own misconduct.^{4(p32)} In those cases, a formal line of duty investigation is required before compensability is denied.

Failure to Follow Prescribed Medical Treatment

Under paragraph B-3, Appendix 3 of *Army Regulation 635-40*,^{7(p66)} the PEB may deny or reduce compensation for Soldiers who fail to comply with prescribed medical treatment. The Army will not compensate the portion of disability that results if a Soldier unreasonably fails or refuses to take prescribed

*For detailed discussions of the structure and processes of the Warriors in Transition program, see the January-March 2008 issue of the *Army Medical Department Journal*, available at <http://www.cs.amedd.army.mil/dasqaDocuments.aspx?type=1>.

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medications; submit to medical or surgical treatment or therapy; or observe prescribed restrictions on diet, activities, or the use of alcohol, drugs, or tobacco.

This reduction or denial of compensation can only occur if the Soldier was clearly and understandably advised of the proper medical course of treatment, and the Soldier's failure or refusal was willful or negligent and not the result of mental disease or a physical inability to comply.

Conditions not Constituting a Physical Disability

The DoD has determined that the conditions presented in the Table do not constitute a compensable physical disability.^{4(pp72-73)}

Rating and Level of Compensation

Once the PEB determines a Soldier is unfit and compensable, the PEB assigns a disability rating

mathematical formula is commonly referred to by practitioners as "fuzzy math."

Section 1642 of the National Defense Authorization Act 08¹ states that the service secretaries shall, to the extent feasible, only use the criteria in the VASRD to rate compensable disabilities, including any applicable interpretations by the United States Court of Appeals for Veterans Claims. Further, service secretaries can only deviate from the rating criteria in the VASRD if the use of such criteria will result in a determination of a greater percentage of disability than would be otherwise determined through utilization of the VASRD.¹⁵

Determination of Tax Free Benefits

For both severance and disability retirement, the PEB will determine that a Soldier is entitled to tax exempt benefits only when their unfitting injuries are combat related, incurred as a direct result of armed conflict, or caused by an instrumentality of war. Soldiers are also entitled to tax exempt benefits if, on September 24, 1975, they were a member or obligated to become a member of an armed force or reserve (of any nation), National Oceanic and Atmospheric Administration, or US Public Health Service.^{4(p36)} The PEB will normally require command corroboration if a Soldier is asserting combat related or instrumentality of war injuries. However, the PEB may accept Purple Heart citations, Combat Infantry Badges, or Combat Action Badges in lieu of command corroboration, depending on the nature of a Soldier's specific injury.

| | |
|--|---|
| Enuresis Sleepwalking and/or somnambulism Dyslexia and other learning disorders Attention deficit hyperactivity disorder Stammering or stuttering Incapacitating fear of flying confirmed by a psychiatric evaluation Airsickness, motion, and/or travel sickness Phobic fear of air, sea, and submarine modes of transportation Uncomplicated alcoholism or other substance use disorder Personality disorders Mental retardation Adjustment disorders Impulse control disorders Sexual gender and identity disorders, including sexual dysfunctions and paraphilias | Factitious disorder Obesity Overheight Psuedofolliculitis barbae of the face and/or neck Medical contraindication to the administration of required immunizations significant allergic reaction to stinging insect venom Unsanitary habits including repeated venereal disease infections Certain anemias (in the absence of unfitting sequelae) including G6PD* deficiency, other inherited anemia traits and Von Willebrand's disease Allergy to uniform clothing Homosexuality |
| *Glucose-6-phosphate dehydrogenase | |
| Conditions which do not constitute a compensable physical disability as determined by the Department of Defense. | |

INFORMAL PHYSICAL EVALUATION BOARD DECISION

percentage for each unfitting condition, according to the present degree of severity, based upon the Veterans Affairs Schedule for Rating Disabilities (VASRD).¹³ In situations where a certain medical impairment is not listed in the VASRD, the PEB will apply an analogous VASRD code which most closely resembles the Soldier's condition. If a case involves 2 or more ratable conditions, the PEB will use a mathematical formula to determine the overall combined rating.^{7(pp67-68)} The

Each case is first considered by an informal, 3-member PEB panel that issues an informal decision on the DA Form 199. An informal decision is based solely upon a paper review of the case, including the Soldier's service medical record, the MEB report, any narrative summaries, available civilian and veterans affairs medical records, and any relevant service performance data (evaluation reports, commander's letters, APFT scorecards).

The PEB can issue the following dispositions:

1. Return to medical treatment facility. The PEB can return a case to the MTF if it determines that the Soldier has not yet reached maximum medical benefit or if additional medical evidence is required to adjudicate the case.

2. Fit for duty. Soldiers with medical conditions that do not prevent them from reasonably performing military duties, including primary military occupational specialty duties, basic soldiering skills, passing an APFT, and deploying will be found fit and retained in the Army.

3. Unfit, separation without benefits. If a Soldier's illness or injury is determined to be noncompensable, he or she will be discharged without entitlement to disability benefits.

4. Unfit, separation with severance pay. Unfit Soldiers with less than 20 years of active federal service and who have compensable conditions with a combined rating of 0% to 20%, will be separated from the Army with severance pay. Severance pay is calculated by $2 \times (\text{monthly base pay}) \times (\text{years of active duty service})$. For RC Soldiers, active federal service is computed by dividing the total number of active duty points by 365. A Soldier may elect length of service retirement in lieu of severance pay if he or she is otherwise entitled to length of service retirement.

Severance or Retirement Pay Decisions

Minimum Severance Pay Provisions under National Defense Authorization Act 08

Section 1646 of the National Defense Authorization Act 08¹ revises the calculation of disability severance pay for those Soldiers who are found unfit, but do not meet the criteria for disability retirement. The new law provides that the minimum number of years used to calculate severance pay shall be 6 years for those injured in a declared tax-free combat zone or during combat related operations, and 3 years for all others. In addition, the Act increased the maximum number of years calculable for severance pay from 12 to 19 years. Service of 6 months is rounded up, and service of less than 6 months is rounded down. The effective date for this provision is January 28, 2008.

No Department of Veterans Affairs Offset in Severance Pay for Combat Zone Incurred Conditions

Section 1646(b) of the National Defense Authorization Act 08¹ states that the Department of Veterans Affairs

will not deduct severance pay received by a service member for unfitting line of duty disabilities incurred in a combat zone or incurred during the performance of duty in combat-related operations. The effective date for this section is January 28, 2008.

Unfit, Permanent Disability Retirement

Soldiers will be permanently retired for disability when their conditions are permanent and stable, and either the combined rating is 30% or higher or they have at least 20 years of active duty service. Permanent Disability Retirement (PDR) entitles Soldiers to all the benefits of a length of service retirement. Retirement pay is calculated by multiplying the combined rating by the Soldier's monthly base pay. By law, Soldiers cannot receive more than 75% of their monthly base pay for disability retirement. For example, an unfit Soldier with a combined rating of 100% can, statutorily, only receive a maximum of 75% of his or her monthly base pay. A Soldier may elect length of service retirement in lieu of PDR if the Soldier is otherwise entitled to a length of service retirement.

Unfit, Temporary Disability Retirement List

Soldiers will be placed on the Temporary Disability Retirement List (TDRL) when their conditions are unstable and their combined rating is 30% or higher, or they have at least 20 years of active duty service. A Soldier on the TDRL receives all the benefits of length of service retirement, including retirement pay. A Soldier on the TDRL with a combined rating of 50% or less receives retirement pay equal to 50% of the Soldier's active duty base pay. A Soldier on the TDRL with a combined rating of 60% or higher receives that percentage of base pay to a maximum of 75%. As discussed above, Soldiers cannot receive more than 75% of their monthly base pay for retirement. By law, Soldiers placed on the TDRL must undergo a periodic 18-month reevaluation by the PEB, with the exception of Soldiers found unfit by reason of post traumatic stress disorder (PTSD). Soldiers found unfit due to PTSD and placed on the TDRL will have a mandatory 6-month review.^{4(p19)} Soldiers with unfitting PTSD may receive PDR rather than TDR only if they have an 80% or greater rating for non-PTSD related conditions. Qualified Soldiers can stay on the TDRL for a maximum of 5 years, however, there is no entitlement for a Soldier to stay on the TDRL for the entire period. The final disposition of TDRL cases may be fit for duty, separation with severance pay, separation

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without entitlement to disability benefits, or permanent disability retirement. A TDRL member found fit for duty upon periodic reexamination by the PEB will be given the option to separate without entitlement to disability benefits and not be required to complete the balance of their active duty or reserve service obligation.^{7(pp47-48)} Therefore, completion of any remaining obligation is subject to the TDRL member's consent.

Election Period and Rebuttals to the Informal Decision

All Soldiers are encouraged to consult with an MEB outreach counsel or Soldiers counsel upon receipt of their DA Form 199. Generally, Soldiers have 10 days upon receipt of their informal PEB decision to file an election in their case, either concur, do not concur, or do not concur and submit a rebuttal. A Soldier can also demand a formal hearing with a personal appearance, or a formal hearing without a personal appearance. Additionally, Soldiers are entitled to assistance with their appeal by a regularly appointed Soldiers counsel. The Soldier may elect to have counsel of his or her own choice at no expense to the government.

Unless a Soldier obtains new medical evidence during their informal PEB election period or can show clear error on their informal DA Form 199, we suggest Soldiers elect "do not concur" and refrain from submitting a rebuttal at that time. Once an assigned Soldiers counsel has had an opportunity to review the service medical record, he or she can later submit a rebuttal statement with supporting evidence at any time prior to a hearing. The PEB can then issue a favorable informal reconsideration without the need for a hearing.

Even if a Soldier is unable to obtain new evidence or show clear error, we generally suggest that all Soldiers initially nonconcur with their informal PEB decision and request a formal hearing. Such a request can be waived later. Assigned Soldiers counsel are provided the same MEB/PEB evidence packet as the board members, as well as access to their client's entire service medical record. Soldiers counsel will review this evidence along with the Soldier's goals to determine if proceeding forward with a formal hearing is advisable.

FORMAL HEARINGS

Formal hearings are held de novo, the PEB is not bound by its previous decisions and recommendations. In addition, neither military nor federal rules of evi-

dence are applied to PEB adjudication. The only standard for submission of evidence is that material submitted to the PEB must be relevant and material to the Soldier's case. Formal hearings are nonadversarial as there is not an opposing counsel representing the PEB.

On the day of the scheduled hearing, it is customary for Soldiers counsel to have a prehearing conference with the presiding PEB board members. The counsel will briefly discuss the merits of their case. Many times this informal discussion will lead to a revised reconsideration in favor of the client. If a hearing is still necessary, both counsel and client will appear before the board for a formal presentation of the case.

During the hearing, the Soldiers counsel makes opening statements highlighting the supporting evidence in their case, performs the initial direct examination, asks any necessary redirect questions after the board members have exhausted their line of questioning, and provides a summation of relevant regulations, evidence, and client testimony. The Soldier will have an opportunity to make a statement just prior to the board's adjournment for deliberations.

Soldiers are entitled to call witnesses to support their case, however, they must be relevant and material to the issues or facts in contention.

CONTINUATION ON ACTIVE DUTY OR ACTIVE RESERVE FOR UNFIT SOLDIERS

Soldiers who are determined unfit may continue, if approved, in a limited duty status in their respective active or reserve component.^{7(p40-46)} Continuation on Active Duty (COAD) and Continuation on Active Reserve (COAR) offer Soldiers the opportunity to continue their military careers and/or possibly qualify for length of service retirement in lieu of disability severance or retirement.

In order for a Soldier to ensure that he or she is considered for COAD or COAR, the Soldier must request consideration in writing. Requests should be provided to the Soldier's PEBLO or Soldiers counsel for inclusion in the PEB file. If the Soldier is found unfit by the PEB, the COAD or COAR request will be forwarded to the appropriate approving authority for action before the Soldier is discharged. COAD and COAR requests are approved and disapproved at the highest levels, either at the Army Human Resources Command or at the National Guard Bureau.

Soldiers must meet one of 3 criteria to qualify for COAD or COAR consideration:

- At least 15 years of active federal service for COAD or at least 15 years of qualifying service for nonregular retirement (ie, “good years” in the Guard or Reserve) for COAR
- Qualified in a critical skill or shortage MOS
- Disability is the result of combat or terrorism

A Soldier who qualifies for consideration will not necessarily be approved for COAD or COAR. Consideration criteria include disability that is not the result of misconduct or willful neglect, or is not incurred while absent without leave; whether the Soldier is capable of working in a normal military environment without adversely affecting the Soldier’s or other’s health or requiring undue loss of time from duty for medical treatment; and whether the Soldier is physically capable of performing useful duty in the MOS for which he or she is currently qualified or is potentially trainable.

Requests for COAD or COAR do not require supporting documentation. However, in order to bolster a request, a Soldier may attach documents such as statements from commanders or supervisors addressing the Soldier’s physical capabilities and requesting that the Soldier’s request be approved, and letters from treating physicians addressing the Soldier’s physical capabilities. Indeed, any evidence which would support a finding of fit should be attached to the COAD or COAR request.

A COAD or COAR may help Soldiers with significant investments in military careers by allowing those Soldiers to continue military service until they are qualified for length of service retirement (20 years). Soldiers with over 15 years of military service who may be discharged because of disability should strongly consider submitting a request. Soldiers with between 18 and 20 years of military service who do not request a COAD or COAR must submit a statement specifically declining COAD or COAR. As an alternative, the Soldier’s PEBLO may submit a statement that the Soldier was counseled and declined to request a COAD or COAR. COAD or COAR denials for Soldiers with at least 18 active duty years or 18 good years toward reserve retirement require Secretary of the Army approval.

APPEAL OF FORMAL PHYSICAL EVALUATION BOARD DECISIONS WHILE ON ACTIVE DUTY

If a Soldier disagrees with the formal PEB decision, there is generally a 10-day election period to submit a rebuttal. If the rebuttal is submitted within the prescribed election period, the PEB will review the rebuttal and may issue a revised reconsideration in favor of the Soldier. If received after the 10-day election period, the PEB will forward the case to the Physical Disability Agency (PDA) for appellate review. Under current policy, the Army PDA will generally accept a rebuttal outside of the 10-day election period only if a Soldier has not yet received their final transition processing orders. The PDA can concur with the PEB decision, nonconcur and modify/reverse the PEB decision, or return the case to the PEB in its entirety.

The PDA designates certain cases for “own motion” (mandatory) review. Currently, the PDA reviews all cases awarded tax-free benefits due to combat-related disabilities in addition to all cases involving post traumatic stress disorder and traumatic brain injuries. Further, the PDA conducts a statistical sample review of all other cases for quality assurance purposes. The PDA’s own motion review can result in an adverse modification of a Soldier’s PEB decision.

The Army Physical Disability Appeals Board (APDAB) is another level of appellate review potentially available to Soldiers prior to separation. Unfortunately, the majority of Soldiers are denied access to this appellate body for procedural reasons. By regulation, Soldiers can only file an APDAB appeal if the PDA modifies or reverses the PEB decision, creating a discrepancy between the PEB and PDA. However, experience has shown that the PDA, rather than issuing a decision inconsistent with the PEB, returns the case to the PEB with a recommendation to issue a new decision consistent with the PDA’s interpretation of the case. This process results in parity amongst the PEB and PDA’s decisions and, ultimately, the Soldier’s inability to file an appeal through APDAB. The PDA has acknowledged this potential for unfairness. Though not required by current regulations, under internal policy set by the current PDA leadership, Soldiers are granted access to APDAB if the PDA remands a case to the PEB, which then subsequently modifies the earlier PEB decision adverse to the Soldier’s interests.

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If an APDAB appeal is unsuccessful, the Soldier can then appeal PEB/PDA action after separation from active duty as discussed below.

APPEAL OF PHYSICAL EVALUATION BOARD OR PHYSICAL DISABILITY AGENCY DETERMINATIONS AFTER SEPARATION OR RETIREMENT

After separation, retired and former Soldiers may seek review of their PEB or PDA determinations through the Army Board for Correction of Military Records (ABCMR), Army Disability Rating Review Board (ADRRB), or the newly created DoD Physical Disability Review Board (DoD PDRB). ABCMR claims must be filed within 3 years of the first knowledge of an error or injustice and after the former Soldier has exhausted all administrative remedies offered by existing laws and regulations. The ADRRB reviews disability percentage ratings upon request for Soldiers who were retired due to physical disability. Requests for ADRRB review must be made within 5 years from the date of retirement.

Section 1643 of the National Defense Authorization Act 08¹ established the DoD PDRB. The PDRB will evaluate cases upon request of a Soldier or through its own motion review where the Soldier was separated with a 20% or less disability rating and was not eligible for retirement. Only Soldiers separated between September 11, 2001, and December 31, 2009, are eligible for this review. The PDRB will consist of a 3-member panel and will make recommendations to the appropriate service secretary. The PDRB can make the following findings:

- Recommendation for no change or modification in disposition
- Recommendation that separation be recharacterized as retirement
- Recommendation for the modification of a disability rating (however, the PDRB is barred from recommending a modification of the disability that would reduce the Rating for that disability)
- Recommendation for the issuance of a new disability rating.

Upon receipt of the PDRB recommendations, the service secretary may modify the records of the individual effective the date of the original PEB.

Department of Defense Instruction 6040.44 designates the US Air Force as the lead DoD component for the establishment, operation, and management of the PDRB for DoD. The PDRB will only conduct a paper review of cases and will not hold in-person hearings. Initially, *Department of Defense Instruction 6040.44* (2008) stated that the PDRB will only review the dispositions of medical conditions previously determined unfitting by the military department PEB. However, under the change incorporated in June 2009, the PDRB is allowed to review all medical conditions, not just those earlier found unfitting.^{16(pp1-2)} Appellants must carefully choose their forum as DoD PDRB appellants may not seek subsequent nor concurrent relief from the ABCMR on the same issue. Further, the PDRB will not review any appeals that were previously adjudicated by the ABCMR on the same issue, with the exception of ABCMR claims filed prior to June 27, 2008 (the original effective date of *Department of Defense Instruction 6040.44*).

Prior to the June 6, 2009, modification to the *Department of Defense Instruction 6040.44*,¹⁶ if the contested separation occurred prior to January 28, 2008 (the date the Defense Authorization Act 08¹ was signed into law), the PDRB would have conducted reviews in accordance with the Veterans Affairs Schedule for Rating Disabilities (VASRD) in effect at the time of separation, *Department of Defense Instruction 1332.39** and any other applicable service regulations in effect at the time of the contested separation. This has since been changed. The DoD PDRB will ignore any DoD and service regulations that were inconsistent with the VASRD in effect at the time of the adjudication. This is a significant change as many of the older DoD and service-specific regulations were inconsistent with the VASRD, yielding lower ratings.

JOINT DEPARTMENT OF DEFENSE/DEPARTMENT OF VETERANS AFFAIRS DISABILITY EVALUATION SYSTEM PILOT PROJECT

On November 26, 2007, the Department of Defense and Department of Veterans Affairs (DVA) implemented the Disability Evaluation System (DES) Pilot^{17,18} for disability cases originating at the 3 major military treatment facilities in the National Capitol

**Department of Defense Instruction 1332.39: Application of the Veterans Administration Schedule for Rating Disabilities.* Cancelled, no longer in effect.

Region: Walter Reed Army Medical Center, National Naval Medical Center, and Malcolm Grow Medical Center (USAF). On September 25, 2008, the Deputy Secretary of Defense and the Deputy Secretary of Veterans Affairs approved the expansion of the DES Pilot to 19 military installations, including 9 Army posts: Fort Meade, Maryland; Fort Belvoir, Virginia; Fort Stewart, Georgia; Fort Polk, Louisiana; Fort Richardson and Fort Wainwright, Alaska; Fort Drum, New York; Fort Carson, Colorado; and Brooke Army Medical Center, Fort Sam Houston, Texas. In November 2009, a further expansion of the program to 6 additional installations was announced, including Fort Benning, Georgia; Fort Bragg, North Carolina; Fort Hood, Texas; Fort Lewis, Washington; and Fort Riley, Kansas.

Key features of the developing DoD/DVA DES Pilot include a single comprehensive medical examination and a single-sourced disability rating. The DVA will conduct a single comprehensive exam and will rate all medical conditions. The military departments will accept the DVA rating for all medical conditions determined unfit for continued military service unless the condition involves noncompliance, misconduct, or a nonservice aggravated medical condition which existed prior to service. The military retains authority to determine if a portion of a Soldier's disability, or its entirety, is a result of an EPTS condition, misconduct, or noncompliance. Soldiers counsel will continue to provide services at all steps throughout the DoD/DVA DES Pilot until separation from active duty.

Once a Soldier receives a permanent P3 profile and achieves maximum medical benefit, he or she is referred for MEB processing. During MEB processing, the Soldier will undergo a comprehensive physical examination conducted by the DVA. An Army physician will then review the DVA exams along with the Soldier's service medical records to determine if he or she has any conditions that fall below Army retention standards. The Army physician will then issue an MEB report. If even one condition falls below Army retention standards or is medically unacceptable, the Soldier will be referred for PEB adjudication to determine if the Soldier is fit for continued duty for each condition falling below medical retention standards.

Cases referred by the MEB will first be informally adjudicated by the PEB to determine fitness. The PEB

will consider the Soldier's MEB report, the DVA's comprehensive exam, as well as the Soldier's commander's statement, profile, recent APFTs, and other performance and personnel documents. The PEB determines which conditions are unfitting; which unfitting conditions are compensable; and whether any unfitting compensable conditions are combat-related or occurred in a declared tax-free combat zone. The PEB's informal findings will be documented on a DA Form 199 and be provided to the Soldier. The Soldier may elect to either concur with the informal findings of fitness, or nonconcur and also request a formal hearing with representation by Soldiers counsel. Alternatively, the Soldier can elect to have a representative of his or her own choice at no expense to the government. If the Soldier is determined unfit, he or she may elect to postpone concurrence or nonconcurrence until receipt of the DVA ratings. If the Soldier does not concur with the fitness determination, Soldiers counsel can help the Soldier identify and gather evidence which might support the accomplishment of their goals. Soldiers counsel may also present this evidence to the PEB on the Soldier's behalf, along with oral arguments during the formal hearing, if elected.

Soldiers can concur with the PEB's informal fitness determination and nonconcur with the DVA rating. Soldiers can also concur with the DVA rating and request a formal hearing to contest the PEB's fitness determination.

All Soldiers determined unfit have a one-time opportunity to appeal their DVA rating, which the Army will accept for disposition purposes (severance versus disability retirement). This one-time rating reconsideration must occur prior to the Soldier's separation. Any successful DVA appeals the Veteran makes after separation will not be accepted for military disposition purposes unless the DVA appeal (notice of disagreement) was filed within 1 year of separation. In addition, if the postseparation appeal is successful, the Veteran must file a claim to change his or her military disposition through the Army Board for Correction of Military Records.

Soldiers counsel can assist service members with reconsideration requests regarding their initial DVA ratings prior to their separation from military service. The request for reconsideration is a paper review by a

The Army Physical Disability Evaluation System

DVA Decision Review Officer (DRO). Soldiers are not afforded an in-person DVA hearing to contest their rating. Further, the DVA DRO will only reconsider evaluations of ratings if new medical evidence is received, or if there is evidence of an error sufficient to warrant reconsideration.

CONCLUSION

Soldiers are best served by MEB outreach counsel and Soldiers counsel who handle physical disability cases on a daily basis. Many factors impact a Soldier's disposition in the Army Physical Disability Evaluation System. There are specific evidence-driven strategies involved with trying to accomplish a Soldier's goal of either continuing his or her military career or maximizing the disability rating. It is important to note that MEB outreach counsel and Soldiers counsel represent Soldiers. They do not advise or represent commanders, nor do they advise or represent the MEB/PEB. The PEB and the PDA are components of the Army Human Resources Command and fall under a different chain of command. Accordingly, neither the PEB nor PDA rate Soldiers Counsel performance for officer or civilian evaluation purposes.

MEB outreach counsel and Soldiers counsel stand ready to assist Soldiers throughout the Army Physical Disability Evaluation System. Offices of Soldiers counsel are located at the Walter Reed Army Medical Center, Madigan Army Medical Center, Brooke Army Medical Center, Evans Army Hospital at Fort Carson, Tripler Army Medical Center in Hawaii, Darnall Army Medical Center at Fort Hood, Landstuhl Regional Medical Center and the Bavaria Warrior Transition Unit (Germany).

POINTS OF CONTACT

Office of Soldiers Counsel

Walter Reed Army Medical Center
(202) 782-1550

Email: soldierscounsel@amedd.army.mil

Landstuhl Regional Medical Center, Germany
DSN 314-486-6049 Comm: 011-49-6371-866049

Bavaria, Germany Warrior Transition Unit
DSN: 476-3358 Comm: 011-49-9662-83-3358

Fort Lewis, Washington
(253) 968-4441/4442
Email: max.peb@amedd.army.mil

Tripler Army Medical Center, Hawaii
(719) 526-5572

Fort Carson, Colorado
(719) 526-5572

Fort Sam Houston, Texas
(210) 221-9392 or (210) 295-0432

Fort Hood, Texas
(254) 287-8887

Offices of MEB Outreach Counsel and Warrior
Transition Legal Assistance

Collocated with Warrior Transition Units at the
medical facilities at the following Army installations:

| | | |
|-------------|---------------|------------------------------------|
| Ft Benning | Ft Hood | Ft Sam Houston |
| Ft Bliss | Ft Knox | Ft Stewart |
| Ft Bragg | Ft Lewis | Heidelberg |
| Ft Campbell | Ft Polk | Tripler Army Medical Center |
| Ft Drum | Ft Richardson | Walter Reed Army Medical Center |
| Ft Gordon | Ft Riley | |

ACKNOWLEDGMENTS

Special thanks to CPT Robert E. Webb, Jr, and MAJ David C. White, authors of "Physical Disability Separation," published in the 1999 US Army Medical Command Legal Deskbook, and Ms Frances Dennis, Policy Advisor of the Physical Disability Agency and author of the "Information Paper: Overview of PDES," dated April 11, 2007, for providing a useful framework and knowledge used in writing this article.

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AUTHOR

Mr Dorotheo is Assistant Chief, Office of Soldiers Counsel and Legal Assistance, Office of the Center Judge Advocate, Walter Reed Army Medical Center, Washington, DC.



Risk Management: The Role of Peer Review in Potentially Compensable Event and Medical Malpractice Claims Processing in the Army Medical Department

LTC Anthony J. Kutsch, JAG, USAR

The May 22, 2009 rapid action revision of *Army Regulation 40-68*¹ did much to distinguish the differing roles and procedures of peer review in the risk management setting from its use in the professional review process at Army medical treatment facilities (MTFs). Patient safety is the ultimate goal of peer review in both peer review tracks. Risk management peer review sometimes runs concurrently with or generates subsequent peer review for professional purposes. However, there are significant differences between the two.

Peer review is a tool used in the risk management (RM) context to further the RM goals of preventing the loss of human, materiel and financial resources, as well as limiting the negative consequences of adverse or unanticipated healthcare events through timely documentation, review, and analysis.^{1(p106)} Peer review in the professional review context is designed for the disposition of clinical privileging/practice actions. Professional peer review can adversely impact provider credentials and therefore requires greater due process protections such as hearing and appeal rights.

Risk management peer review is governed by chapter 13 of *Army Regulation 40-68*^{1(pp108-113)} and is triggered either by occurrence of a potentially compensable event (PCE), filing of a medical claim, or notification of payment of a claim settlement or award. In each of these cases risk management peer review is a confidential quality assurance protected process that requires the multidisciplinary cooperation of legal, clinical, and quality management administrative staff members. The Army Medical Command (MEDCOM) Quality Management Division accomplishes its oversight and corporate tracking responsibilities for risk management peer reviews through the use of the Centralized Credentials Quality Assurance System

database. Chapter 13 of *Army Regulation 40-68* specifies frequent and incremental MTF reports/notifications into the Centralized Credentials Quality Assurance System at every step of the process, from discovery of a PCE or notice of a claim until final resolution.

POTENTIALLY COMPENSABLE EVENT INITIATED RISK MANAGEMENT PEER REVIEWS

A PCE is defined in *Army Regulation 40-68* as

an adverse event that occurs in the delivery of health care or services with resulting injury to the patient. It includes any adverse event or outcome, with or without legal fault, in which the patient experiences any unintended or unexpected negative result. It pertains to all patients regardless of beneficiary status....^{1(p167)}

This definition includes cases involving death or disability of a military member as a result of medical or dental care, all of which are investigated as PCEs under *Army Regulation 40-68*.

Departmental/Service Level Peer Review

PCEs are most commonly identified by MTF risk managers from incident reports* originating at the point of care, or from the verbal or written statements of patients, family members, or healthcare staff. An initial departmental/service level peer review is conducted as soon as possible in order to capture information about the PCE while memories are fresh and records and personnel are still readily available. This peer review is conducted for every healthcare provider significantly involved in the PCE. The initial peer review is often conducted by an individual peer reviewer who is not involved in the case in question. *Army Regulation 40-68* defines a peer as "an individual from the same professional discipline/

*Department of the Army Form 4106

specialty to whom comparative reference is being made.”^{1(p166)} Regional medical commands assist in obtaining peer reviewers from other MTFs if a facility lacks sufficient personnel to conduct an impartial and unbiased peer review. Initial departmental/service level peer reviews investigate the clinical facts and circumstances surrounding the PCE and render standard of care and attribution determinations that are forwarded to the MTF risk management committee for consideration.

Risk Management Committee Level Peer Review

The risk management committee peer review likewise investigates the clinical facts and circumstances surrounding the PCE and renders a standard of care (SOC) determination (“SOC-Met,” “SOC-Not Met,” or “Indeterminate”) and an attribution determination for each significantly involved healthcare provider. The specific rationale for these findings is included in the report, along with follow-up actions related to systems or process issues, any apparent trends with recommendations for improvement, and the status of any pending claims. The risk management committee report/minutes may also include recommendations for the MTF credentials committee for privilege/practice related actions (potentially initiating the alternative track of peer reviews that occur under the professional review system established in chapter 10, *Army Regulation 40-68*^{1(p76)}). Practitioner-specific findings are reported to the MTF credentials committee and/or department chief (in the case of a nonprivileged professional), and the risk management committee report/minutes are then forwarded through quality management channels to the MTF commander. When required, regional medical commands provide support for MTFs lacking local risk management committee oversight.

Due Process Considerations

MTF-level risk management peer reviews entail only minimal due process procedures: significantly involved healthcare providers are notified in person or by certified return-receipt requested mail of the pending peer review, given access to medical records and redacted relevant documents, and given the opportunity to submit written statements. Local policy may allow in-person presentation of information by significantly involved providers, but will not permit their presence at risk management committee deliberations. The administrative nature and non-

adversarial data collection and preservation purposes of PCE-initiated peer reviews explain the absence of greater formality or heightened due process protections.

If a PCE does not ripen into a medical malpractice claim or form the basis of a separate professional review for adverse privileging action, then the PCE-initiated risk management peer review concludes at the MTF level with the completion of required Centralized Credentials Quality Assurance System notifications and the report to the MTF commander. Exceptions to this are cases of a death or disability to a military member as a result of medical or dental care, all of which go beyond the MTF for further peer review and potential Defense Practitioner Data Bank reporting.

MEDICAL MALPRACTICE RISK MANAGEMENT PEER REVIEWS

Medical malpractice peer reviews are triggered by the notification of a claim alleging substandard care to the MTF from the US Army Claims Service or the Center Judge Advocate or Staff Judge Advocate office at which the claim was filed. This includes every claim of malpractice filed under the Federal Tort Claims Act,² the Military Claims Act,³ the International Claims Settlement Act,⁴ or the Foreign Claims Act.⁵

The goals and procedures of the medical malpractice peer review at the MTF level are identical to those of the PCE-initiated peer review described above. In fact, an MTF peer review will not be repeated when a medical malpractice claim arises out of the same care/provider reviewed previously in a properly conducted PCE-initiated peer review.

Peer review ceases at the MTF level unless a medical malpractice peer review instigates a separate professional peer review under Chapter 10 of *Army Regulation 40-68*^{1(pp71-93)} or there is a payment based on the underlying claim. Cases in which a medical malpractice claim results in a monetary award (“paid claim” cases) are elevated beyond the MTF for additional stages of peer review. Peer reviews that occur beyond the MTF take on an additional objective: facilitating the determination of whether The Surgeon General of the Army has a statutory requirement to file a report to the National Practitioner Data Bank (NPDB) under the Healthcare Quality Improvement Act of 1986.⁶ Notification of a paid claim is of

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particular importance as it starts the clock running on a 180-day period during which The Surgeon General must make a reporting determination or the NPDB report becomes mandatory under *Department of Defense* [regulation] 6025.13-R.^{7(p76)} Paid claims include any monetary award arising out of claim settlement by US Army Claims Service, a host nation (International Claims Settlement Act Claims), or a claim settled or adjudicated by the Department of Justice.

Peer review also continues beyond the MTF for cases of death or disability to a military member as the result of medical or dental care, regardless of whether there has been a paid claim. Medical malpractice claims by the service members themselves are barred by the Feres doctrine.* However, these cases are referred into the risk management peer review system when a Medical Evaluation Board (MEB) or Physical Evaluation Board (PEB) finds that care rendered to the service member deviated from the standard of care. A “standard of care not met” determination and attribution of responsibility in these cases may result in a report to the Defense Practitioner Data Bank rather than the NPDB.

Unlike their civilian counterparts, healthcare providers in the military healthcare system are afforded multiple peer reviews when they are the subject of a NPDB report. MEDCOM Quality Management Division coordinates peer review that occurs above the MTF level. All cases are reviewed by a discipline/specialty clinical expert designated by The Surgeon General who will either submit a written report to or participate as a member of the MEDCOM Special Review Panel (SRP).

The SRP consists of at least 3 privileged providers, at least one of whom is from the same specialty or discipline as the provider under review. The provider under review is notified of the pending SRP and typically given 15 days to submit any additional written information on his or her behalf. The SRP review is an administrative procedure to which the rules of evidence are not applied. The SRP considers

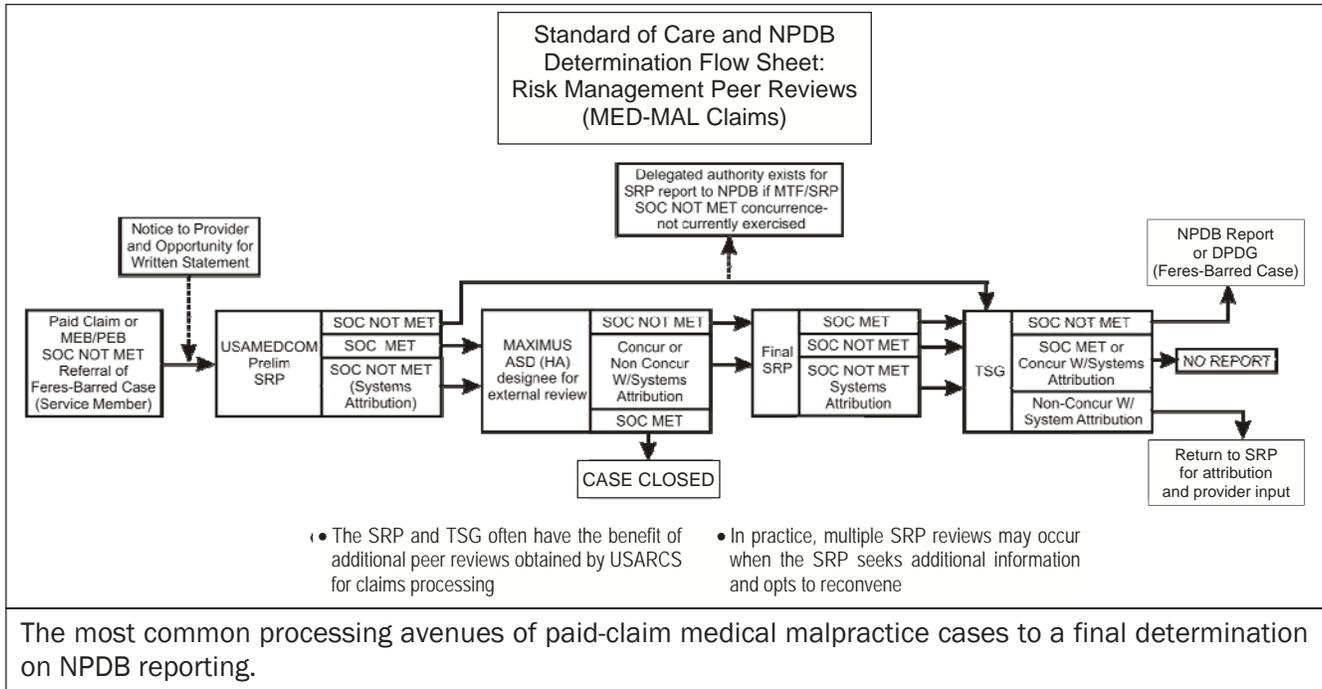
*The Feres doctrine is the term describing the result of a case⁸ which generally precludes successful suits by service members for personal injury or death that is incurred incident to service, whether or not they were suffered in the performance of their duties.

any new information submitted by the provider along with all previous peer reviews, investigative reports, relevant clinical records, and a summary of the administrative claim adjudication or litigation disposition documents.

An additional external peer review is sought whenever an initial SRP peer review makes a “standard of care-met” (SOC-Met) determination, whenever there is a SOC Not-Met determination but it is attributed to a “systems error” rather than an individual provider, or at the discretion of the SRP. The current designee by the Assistant Secretary of Defense (Health Affairs) for external peer review is MAXIMUS, Inc (11419 Sunset Hills Road, Reston, Virginia 20190). The SRP reconvenes for a second and usually final time to consider the results of the external peer review by MAXIMUS. If necessary due to some unresolved issue in the case record, the SRP may elect to seek additional information and hold additional reviews. The SRP makes a SOC determination and attribution by majority vote as well as a recommendation on NPDB reporting to The Surgeon General. The Surgeon General is the sole reporting authority to the NPDB. Regulations allow delegation of reporting authority to the SRP for cases in which all levels of peer review agree SOC Not-Met, however this delegation is not currently exercised.

Section 14-3 of *Army Regulation 40-68*^{1(pp114-115)} sets forth procedures, specific criteria, and legal review requirements for reports to the NPDB. In order for there to be an NPDB report, there must be a finding that the provider committed a deviation from the standard of care and that the deviation was the cause of harm that gave rise to a payment. An NPDB report of a trainee requires additional findings that the trainee acted outside the scope of his or her practice or that his or her deviation from standard of care was not reasonably foreseeable by a supervisor. The most common processing avenues of paid-claim medical malpractice cases to a final determination on NPDB reporting are shown in the Figure.

The Army risk management peer review system is designed to carefully balance numerous important interests: patient safety, data collection and preservation, protection of healthcare provider credentials and reputations, and accountability and disclosure to the public in the case of substandard care. The system



relies heavily on frequent communication with and oversight by the MEDCOM Quality Management Division through the Centralized Credentials Quality Assurance System, as well as the coordination of risk managers, Army lawyers and unbiased peer reviewers.

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AUTHOR

LTC Kutsch is a Drilling Individual Mobilization Augmentee currently assigned to the US Army Medical Command Office of the Staff Judge Advocate, Fort Sam Houston, Texas.



Articles published in the *Army Medical Department Journal* are indexed in MEDLINE, the National Library of Medicine's (NLM's) bibliographic database of life sciences and biomedical information. Inclusion in the MEDLINE database ensures that citations to *AMEDD Journal* content will be identified to researchers during searches for relevant information using any of several bibliographic search tools, including the NLM's PubMed service.



Consent to Medical Treatment

Karin Waugh Zucker, MA, JD, LLM, MFS
Martin J. Boyle, JD
COL Thomas C. Jefferson, MC, USA
MAJ Dennis J. Ratliff, JAG, USAR

BACKGROUND

In 1914, in the case of *Schloendorff v Society of New York Hospital*, Judge Benjamin Cardozo stated:

Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault [today, a battery] for which he is liable in damages.¹

This judicial determination of the primacy of individual autonomy has grown into the common law doctrine of informed consent.² While *Schloendorff* and earlier cases, such as *Slater v Baker and Stapleton*,³ asked only if the patient had consented to the particular procedure, later cases have looked to see if consent was sufficient to be considered "informed."

*Canterbury v Spence*⁴ is perhaps the leading case on informed consent. After a statement of the facts, it reads much like a law review article, and explores the key questions regarding informed consent. What is the origin of the physician's duty to disclose? What is the scope of the duty? Is the duty physician-centered, or patient-centered? What are the exceptions to the duty? What is the role of causality? *Canterbury*, by itself, provides the reader an excellent basis in the law of informed consent.

The logical and judicially recognized principle converse to informed consent might well be called "informed refusal" and the entire subject regarded as "informed decision-making." While an in-depth examination of informed refusal is beyond the scope of this article, it must be pointed out that informed consent and informed refusal should be regarded as two sides of the same coin. To speak of informed consent without recognizing a right of informed refusal is to render the former meaningless.

CONSENT GENERALLY

Simply stated, the general rule is that informed consent is required before medical care or treatment can be given.⁵ The definition or extent of that consent is a matter of state law.⁶ It is generally accepted, however, that consent has 3 elements: decision-making capacity, information, and voluntariness.⁷ The elements of decision-making capacity and information can be further divided. Decision-making capacity has 2 subelements: legal age,⁸ and sufficient or appropriate understanding. Information has 4 subelements: the treatment or procedure that is proposed; the hoped-for benefits; the risks; and the reasonable alternatives, including the likely effect of no medical intervention at all. Even when the subelements of information are defined, one is still left with the question of how these are to be determined. There are basically 2 ways. The older is to ask, "What would a reasonable and prudent physician disclose in such a situation?" The newer requires the physician to ask, "What would a reasonable patient in such a situation want to know, taking into account the physician's specific knowledge about this particular patient?" The third element of, or requirement for consent, voluntariness, cannot be further divided. Clearly, voluntariness is the absence of coercive conduct, but the extent to which the individual can be influenced and still make a voluntary decision is debated.

Decision-making capacity or incapacity and competence or incompetence are not the same things, although the terms are often used interchangeably. Capacity/incapacity is a medical determination of cognitive capability, including the ability to make meaningful medical decisions. Competence/incompetence is a legal determination. An individual may be incompetent by reason of age (not having attained the statutory age of majority in a state), or mental status.

In most real life situations, no one seeks a legal determination of competence or incompetence. Further, there is no standard definition of capacity for physicians to rely upon.⁹ Boyle tells us, however, that consideration of capacity must include “the individual abilities of the patient; the requirements of the task at hand; and the consequences likely to flow from the decision.”^{9(p67)}

The terms “de jure incompetence” and “de facto incompetence” are also used. A de jure incompetent is one who has been adjudged an incompetent by a court; while a de facto incompetent is one recognized as incompetent, but not so adjudged by a court. As Berg and her colleagues point out:

Most cases do not warrant...legal proceedings. The issues often are not complex, and the cost of legal proceedings is great.^{8(p187)}

Generally, a parent or legal guardian must give consent for a minor child. An individual appointed as the attorney-in-fact under a durable power-of-attorney for medical care or the next-of-kin, perhaps acting under a state’s statutory scheme, typically acts for an incompetent adult.

If there is a general rule requiring informed consent to medical care, obviously there are exceptions. Briefly those are:

- Care rendered in an emergency when consent cannot be obtained.
- Care rendered in reliance upon therapeutic privilege.
- Care rendered pursuant to discovery, during surgery, of an unanticipated, dangerous condition.
- Care rendered in reliance upon a specific waiver.
- Care rendered pursuant to law, such as the pre-school immunization of children, or lawful regulation.
- Care rendered pursuant to the order of a court of competent jurisdiction.

CONSENT IN MILITARY FACILITIES AND IN THE MILITARY

Paragraph 5.2.1. of *DoD Directive 6025.13*¹⁰ mandates that all facilities providing care to DoD beneficiaries

maintain accreditation by The Joint Commission* (TJC). Accordingly, TJC standards apply in military treatment facilities. The Joint Commission Ethics Rights and Responsibilities Standard R1.01.03.01 could not be more direct. It simply states: “Informed consent is obtained.”^{11(p328)} Standard R1.01.02.01 states “Patients have the right to refuse care, treatment, and services in accordance with law and regulations.”^{11(p326)} Individuals, who would otherwise be treated as minors were they not in military service, are considered to be emancipated and capable of consent as if they were adults,^{12(p5)} subject to command aspects of medical care for Soldiers as described in *Army Regulation 600-20*.¹³

Medical care furnished without proper authority or consent may constitute an assault and battery under Article 128, Uniform Code of Military Justice,¹⁴ and, conceivably, a military healthcare provider could be so charged. That is, however, not common. Typically, the wrong is considered to be a negligent act. If the individual who believed himself wronged were a military member incident to service at the time of the injury, the Feres doctrine[†] prohibits him from successfully suing the government, such as recovering monetary damages, under the Federal Tort Claims Act,¹⁶ which protects the healthcare provider (military, General Schedule employee, and many contractors) who negligently caused the injury from personal liability. If the injury occurred overseas, recovery under the Military Claims Act¹⁷ is similarly barred, as is recovery from the healthcare provider. If the individual who believed himself wronged by a negligent act were a proper plaintiff (a civilian), he might seek and recover monetary damages from the government under the Federal Tort Claims Act or, if the wrong had occurred overseas, by a claim under the Military Claims Act. Again, the healthcare provider would be immunized from personal liability if his or her act were characterized as negligence.

Soldiers

Army Regulation 600-20 addresses this subject in a straightforward fashion. Subparagraph 5-4a. states:

Necessary medical care. A Soldier on active duty or active duty for training will usually be required to

*The Joint Commission (One Renaissance Blvd, Oakbrook Terrace, Illinois 60181) is a private sector, US-based, not-for-profit organization founded in 1951. The Joint Commission operates accreditation programs for a fee to subscriber hospitals and other healthcare organizations.

†The Feres doctrine is the term describing the result of a case¹⁵ which generally precludes successful suits by service members for personal injury or death incurred incident to service, whether or not they were suffered in the performance of their duties.

Consent to Medical Treatment

submit to medical care considered necessary to preserve his or her life, alleviate undue suffering, or protect or maintain the health of others....^{13(p36)}

Care that “may” be provided without the service member's consent includes emergency care, immunizations, isolation and quarantine, detention for necessary medical care or to prevent harm to the service member or others, diagnostic medical care, and physical and other examinations. If an individual refuses care that is deemed necessary but is of a type that would not be required over his or her objection, that individual is typically referred to a medical board.

Family Members

Family members who are not themselves military members will be afforded the same rights with regard to informed consent as if they were in a civilian hospital. The law of the state where the facility is located applies unless there is federal law on point or unless a Status of Forces Agreement provides to the contrary.^{12(p3)} Situations where federal law clearly applies include restrictions on abortions and physician-assisted suicide.¹⁸

Special Situations

Consent for and by Nonmilitary Minors

Most states have statutes addressing consent by minors. Some provide different ages of consent for different procedures. Many allow a lower age of consent for treatment of sexually transmitted diseases than for other purposes. Some states allow physicians to decide whether a minor is sufficiently mature to consent to a particular procedure. Other states have laws which address minority itself, specifying whether certain situations such as marriage or childbirth emancipate a minor. *Army Regulation 40-400* states that if law does not prohibit consent by a minor, the healthcare provider will determine whether the minor is sufficiently mature to consent to a particular procedure and, if that determination is in the affirmative, no parental consent is necessary.^{12(pp4-5)}

Reliance on Surrogate Decision-Makers

According to *Army Regulation 40-400*,^{12(pp3-4)} absent an emergency, consent must be obtained from or on behalf of a nonmilitary person. That consent may be based upon a judicial determination of incompetency and appointment of a guardian, a power-of-attorney for medical care, or a statutory scheme setting forth

individuals who may consent for incompetents. In the absence of such a statutory scheme, the consent of the spouse or next-of-kin will be required except in emergencies.

Involving Relatives in the Decision-Making Process

Privacy laws may well prohibit discussing the specifics of a patient's condition with family members even when that discussion would seem to be in the patient's best interest. For that reason, physicians should be encouraged to talk with their competent patients about including a family member in discussions when the physician believes it to be necessary. If the patient consents to that, the physician should make an appropriate note in the patient's chart and have the patient complete and sign any forms required.

Sterilization of Incompetents

Healthcare providers are required to seek legal advice about the right of a parent or guardian to consent to the sterilization of an incompetent, either a minor or a mentally retarded adult who is deemed to lack decision-making capacity. There is no pat answer; this too is a matter of state law. Suffice it to say that the pendulum has swung far back from the time Oliver Wendell Holmes authorized the sterilization of Carrie Buck, saying, “Three generations of imbeciles are enough.”¹⁹

CONCLUSION

A search of a medical school library and of several libraries of allied health schools indicated there was little new in the law of informed consent. It is well settled that, absent one of the exceptions, there must be consent and it must be informed. What constitutes the informational element is a matter of state law but is generally well set out in *Canterbury v Spence*.⁴ There appears to be some academic interest in considering not the informational element of informed consent but the question of comprehension. Is it enough that the information is given to an individual of normal intelligence? Should healthcare providers also be looking at what patients understand? What is the reading level of the average American; must consent forms, to be meaningful, be written at, or below, that level? Is bad news absorbed as well as neutral information or good news? How much information can be assimilated in one visit with a healthcare provider? Should patients be encouraged to bring a family member to appointments, so that there is someone with

whom to discuss the information received at the visit? As the law continues to develop in this area, we will wrestle with these questions and others in an attempt to define comprehension, rather than information.

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AUTHORS

Ms Zucker is an Associate Professor, Army-Baylor University Graduate Program in Health and Business Administration, Fort Sam Houston, Texas.

Mr Boyle is an attorney with the Department of Veterans Affairs, Audie L. Murphy Hospital, San Antonio, Texas.

COL Jefferson is Assistant Chief, Department of Clinical Investigation, Brooke Army Medical Center, Fort Sam Houston, Texas and a Consultant in Medical Ethics to The Surgeon General.

MAJ Ratliff is a student in the Army-Baylor University Graduate Program in Health and Business Administration, Fort Sam Houston, Texas.



Medical Futility

Mark P. Sposato, JD

INTRODUCTION

What is medical futility and who decides? Over the past few years, several states have enacted medical futility statutes which allow health care providers to refuse a patient's request for life-sustaining medical treatment where such treatment will not provide significant benefit or would be contrary to generally accepted health care standards. Notwithstanding these legislative initiatives, media accounts illustrate the continued difficulty of presuming to answer ethical dilemmas through legal methodologies and judicial intervention.

DEFINITIONS

"Life-sustaining treatment" means treatment that, based on reasonable medical judgment, sustains the life of a patient and without which the patient will die. The term includes both life-sustaining medications and artificial life support, such as mechanical breathing machines, kidney dialysis treatment, and artificial nutrition and hydration. The term does not include the administration of pain management medication or the performance of a medical procedure considered to be necessary to provide comfort care, or any other medical care provided to alleviate a patient's pain.¹

The term "medical futility" generally refers to interventions that are unlikely to produce any significant benefit for the patient.² Two kinds of medical futility are often distinguished: quantitative futility, where the likelihood that an intervention will benefit the patient is exceedingly poor; and qualitative futility, where the quality of benefit an intervention will produce is exceedingly poor.

HISTORICAL BACKGROUND OF MEDICAL FUTILITY

The concept of medically futile treatment can be traced back to the time of Hippocrates. Ancient Greek healers suggested that the 3 goals of medicine were cure, relief of suffering, and the refusal to treat those "overmastered by their illness."³ Patients were

admonished not to ask healers to attempt that which was impossible to medicate. The text also relates that to attempt futile treatment was to display an ignorance "allied to madness." The concept of medical futility has been counterbalanced by the rapid advance of medical science, especially in the last several decades beginning in the 1960s, when life-sustaining medical treatments such as the mechanical ventilator became available.

The case of Karen Ann Quinlan was the first in a series of decisions establishing the so-called right to die.⁴ At the age of 21, Quinlan lapsed into a coma after coming home from a party. Although Quinlan was removed from active life support over the objection of her doctors in 1976, she continued to live in a coma for almost a decade until her death from pneumonia in 1985.

The Quinlan case was followed in 1987 by the case of Nancy Cruzan.⁵ In January of 1983, Cruzan lost control of her car, was thrown from the vehicle and landed face down in a water-filled ditch. Paramedics found her with no vital signs, but they resuscitated her. After several weeks of remaining nonresponsive in a coma, she was diagnosed as being in a persistent vegetative state (PVS). Surgeons inserted a feeding tube for her long-term care. Her husband and parents waited for a more substantial recovery, but eventually, after 4 years, accepted that there was no hope. Her parents eventually asked to have Cruzan's feeding tube removed, but the hospital demanded a court order to that effect. The case made its way to the US Supreme Court which, in 1992, concluded that the US Constitution grants a competent person the right to refuse lifesaving hydration and nutrition. The Court noted that "most state courts have based a right to refuse treatment on the common law right to informed consent...or on both that right and a constitutional privacy right." The Court also held that states may require "clear and convincing evidence" with regard to a person's wishes, and that a state may properly decline to make judgments about the quality of a particular

individual's life and simply assert an unqualified interest in the preservation of human life to be weighed against the constitutionally protected interests of the individual.

After the right-to-die cases established patient autonomy, physicians began to assert that life sustaining medical treatment should be withdrawn or withheld because such treatment no longer met the legitimate goals of medicine and was thus "futile." In the *Wanglie* case⁶ doctors recommended terminating mechanical ventilation for an 86-year old woman in a PVS on futility grounds.⁷ In the *Baby K* case,⁸ physicians and a hospital ethics committee argued in 1993 that mechanical ventilation of an anencephalic child was "futile" and served "no therapeutic or palliative purpose" and was otherwise medically unnecessary and inappropriate. In both cases, courts came down in favor of families being the final arbiter as to the appropriateness of continuing or stopping treatment that might be considered medically futile.

However, the patient's absolute right to determine his or her course of treatment began to erode when, in 1995, a Massachusetts court found in favor of a physician's decision to withhold life-sustaining treatment.⁹ Catherine Gilgunn was 71 years of age in 1989, when she suffered the hip injury that would ultimately lead to her death. At the time of her injury, she already suffered from the effects of 3 prior broken hip repairs, diabetes, heart disease, chronic urinary infections, Parkinson's disease, and a stroke, and had recently undergone treatment for breast cancer. Her daughter allowed her to delay seeking medical attention for the new hip injury for several weeks, and before surgery could occur, Mrs Gilgunn suffered a number of seizures, resulting in brain damage and coma. With the approval of father and siblings, the daughter was designated Mrs Gilgunn's surrogate. After consulting the hospital's Optimum Care Committee (OCC), and despite the fact that the surrogate had requested that "everything be done," Mrs Gilgunn's physician placed a DNR order in her chart. Members of the OCC felt that the family's opinion was not relevant since CPR was not a genuine therapeutic option, and Mrs Gilgunn should not suffer what they considered to be mistreatment simply because the family was not prepared for her death. After the hospital's legal division approved the DNR order, the doctor started weaning her from the ventilator without the surrogate's permission, and with the DNR on her chart. Mrs Gilgunn died 3 days later. At the time of her

death, the surrogate was attempting to arrange for her mother to be transferred to a long-term facility. The surrogate brought the case to court, charging that the hospital had caused the family mental pain and suffering. A jury ultimately rejected the family's claims, finding in favor of the hospital and physicians.

In 1993, the National Conference of Commissioners on Uniform State Laws completed drafting the Uniform Health Care Decisions Act (UHCDA).¹⁰ The overall objective of the UHCDA is to encourage the creation and enforcement of advance health care directives and to provide a means for making health care decisions for those who may have failed to adequately plan for them. New Mexico and Maine adopted the UHCDA in 1995, and the following states have since adopted a combined advance directive statute modeled after the UHCDA: Alabama, Alaska, Arizona, California, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Kentucky, Maryland, Minnesota, Mississippi, New Hampshire, New Jersey, Oklahoma, Oregon, Tennessee, Utah, Vermont, Virginia, West Virginia, and Wyoming. The UHCDA generally requires that health care providers comply with patient and surrogate health care decisions. However, the UHCDA also provides that a healthcare provider may decline to comply with an individual instruction or healthcare decision that requires "medically ineffective" health care or health care contrary to generally accepted health care standards. The Act also allows a health care provider to decline to comply for "reasons of conscience." Finally, while the model UHCDA generally confers immunity to health care providers and institutions for acting in good faith and in accordance with generally accepted health care standards, it does not confer immunity to health care providers or institutions for the unilateral exercise of medical discretion.

In 1994, the American Medical Association's (AMA) Council on Ethical and Judicial Affairs opined:

Physicians are not ethically obligated to deliver care that, in their best professional judgment, will not have a reasonable chance of benefiting their patients. Patients should not be given treatments simply because they demand them. Denial of treatment should be justified by reliance on openly stated ethical principles and acceptable standards of care, as defined in Opinion 2.03, "Allocation of Limited Medical Resources," and Opinion 2.095, "The Provision of Adequate Health Care," not on the concept of "futility," which cannot be meaningfully defined.¹¹

Medical Futility

In 1998, the AMA followed its 1994 medical futility definition with an opinion which set out proposed guidelines for physicians to follow:

When further intervention to prolong the life of a patient becomes futile, physicians have an obligation to shift the intent of care toward comfort and closure. However, there are necessary value judgments involved in coming to the assessment of futility. These judgments must give consideration to patient or proxy assessments of worthwhile outcome. They should also take into account the physician or other provider's perception of intent in treatment, which should not be to prolong the dying process without benefit to the patient or to others with legitimate interests. They may also take into account community and institutional standards, which in turn may have used physiological or functional outcome measures.¹²

CASE STUDY

Emilio Gonzales was an 18-month-old child afflicted with Leigh's Disease when he died in the Pediatric Intensive Care Unit (ICU) at Children's Hospital in Austin, Texas, in May 2007. At the time of his death, Emilio could not see, speak, or eat. A ventilator breathed for him, and he was kept mostly asleep by a combination of drugs administered for palliative purposes. According to one media account, when Emilio's 23-year-old mother held him in her arms, he would sometimes make facial expressions that the mother would say were a smile. At the same time, an ICU nurse standing next to the mother thought that Emilio was grimacing in pain.¹³

Emilio's medical condition became newsworthy when a dispute arose between the hospital and Emilio's mother in regard to the child's course of treatment. Without mechanical respiration, treating physicians believed that Emilio would die within minutes or hours. The hospital contended that keeping the child alive on a ventilator was painful for him and useless against his illness, a rare progressive and fatal neurometabolic disorder. Mrs Gonzales disagreed and wanted to keep her son on the ventilator, allowing him to die "naturally, the way God intended." As the result of complications during her pregnancy, Mrs Gonzales could not have more children. She believed that her Catholic faith compelled her to keep her son alive, regardless of doctors' beliefs that Emilio could not recover and continued treatment was prolonging his suffering. The cost of Emilio's continuing care was paid by Medicare and Medicaid.

The Texas Children's Hospital next convened its ethics committee, which concluded that Emilio's case was medically hopeless. The hospital then gave notice to Mrs Gonzalez that treatment would be withheld after 10 days, during which period she could attempt to find another facility which would be willing to take over Emilio's care. The hospital administrators contacted 31 facilities in an attempt to transfer Emilio without success. After the hospital extended the deadline once, Mrs Gonzales, with the assistance of several right-to-life organizations, obtained a temporary restraining order from a county probate judge. The judge appointed a guardian ad litem to represent Emilio's interests and scheduled a hearing to consider a request by Mrs Gonzales to continue the restraining order. Emilio eventually died before the hearing commenced, shortly before he reached 19 months of age. He spent his last 5 months on life support.

THE TEXAS ADVANCE DIRECTIVES ACT OF 1999

The Texas Advance Directives Act (TADA)¹ seeks to incorporate a due-process standard similar to that proposed by the American Medical Association when a provider refuses to honor a surrogate's request for continued life-sustaining medical treatment. The multistage review process begins with review by the hospital ethics or medical review committee. Life-sustaining treatment must be continued during the review process. The person responsible for making treatment decisions for the patient must be provided with 48 hours advance notice of the review process, and given an opportunity to attend the committee meeting. Once a decision is reached regarding the patient's care, the committee is required to provide written notification of the decision to the person responsible for making decisions for the patient. If the committee agrees with the physician's decision to withdraw life-sustaining treatment from the patient, the physician is required to make a reasonable effort to transfer to a physician or facility willing to continue the patient's care. The patient must be provided available life-sustaining treatment pending transfer. However, the physician and hospital are not obligated to provide life-sustaining treatment the tenth day after the written decision of the ethics committee is provided to the person responsible for making the patient's health care decisions, unless ordered to do so by an appropriate county or district court.

The so-called “safe harbor” provision of the TADA provides that if the treating physicians, other health care providers, and the hospital follow the procedure outlined in the TADA, they are immune from civil liability for withdrawing life-sustaining treatment from a patient. These parties are also not subject to any criminal liability or disciplinary action by licensing boards, unless they failed to exercise “reasonable care.” The limitation on liability provision defines the standard of care (TADA §166.160(c)) which shall be exercised as

...that degree of care that a physician, health care facility, or health care professional, as applicable, of ordinary prudence and skill would have exercised under the same or similar circumstances in the same or a similar community.

OTHER STATE MEDICAL FUTILITY STATUTES

Several states have enacted limited medical futility provisions within their healthcare statutes.

In Virginia, when a physician determines that medical treatment is “medically or ethically inappropriate,” the physician is required to inform the patient or the patient’s designated decision-maker of such determination and the reasons for it, and if a conflict results, the physician must make “a reasonable effort” to transfer the patient to another physician, and provide the patient or decision-maker at least 14 days to effect such transfer.¹⁴ Life sustaining care must be continued during the pendency of the transfer waiting period. The Virginia statute also contains a safe harbor provision. The Maryland statute provides that a healthcare provider who “intends not to comply with an instruction of a health care agent or a surrogate” is required to inform the person giving the instruction that the provider declines to carry out the instruction; that another health care provider may be requested; the health care provider will make “every reasonable effort” to transfer the patient to another health care provider; will assist in the transfer; and, pending transfer, will comply with the instructions of the patient or designated surrogate.¹⁵ The Maryland statute contains a general safe harbor provision for health care providers who withdraw or withhold health care as authorized under the statute.

California’s probate code authorizes a healthcare provider to decline to comply with an individual health

care decision or instruction that requires “medically ineffective” health care or “health care contrary to generally accepted health care standards applicable to the health care provider or institution.”¹⁶ The statute also requires the healthcare provider to inform the patient or surrogate, make all reasonable efforts to assist in transferring the patient to another physician or facility, and to continue care until transfer can be effected. The California statute does not contain a safe harbor provision.

SOCIETAL CONCERNS ASSOCIATED WITH THE CONCEPT OF MEDICAL FUTILITY

The use of increasingly scarce healthcare resources to provide life-sustaining medical treatment which prolongs life but may worsen the quality of that life may not be in the best interests of society. Some medical ethicists now believe that healthcare providers not only have a duty to inform patients, their families, or their surrogates about the known or anticipated outcomes of medical care, but they also have a duty to inform when an intervention may be medically futile and palliative care should be initiated so as to conserve resources for the entire community.

The 1990 Patient Self Determination Act¹⁷ requires healthcare providers to ask patients whether they have an advance directive, to include a do-not-resuscitate order. A new trend has also been observed whereby healthcare providers encourage patients in appropriate cases to make an Acceptance of Natural Death request when interventions are deemed to be medically futile.¹⁸

Some common criticisms leveled against the ethical concept of medical futility include: medical futility is an attempt to increase the power of the physician over the patient, contrary to the concept of patient autonomy; no professional or societal consensus has been achieved in regard to the definition of medical futility; medical futility is a useless concept because empirical treatment data cannot be applied with certainty to any given patient; medical futility threatens the free exercise of religion (eg, hoping for a miracle); and rationing and medical resource allocation will ultimately determine medical futility. These criticisms should be considered and addressed by hospital ethics committees evaluating the effectiveness of life-sustaining medical treatments.

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CONCLUSION

In the absence of either professional or societal consensus about the definition of medical futility, unilateral decision statutes provide a legal basis to withhold life-sustaining medical treatment where such treatment would not provide significant benefit or would be contrary to generally accepted health care standards. In the absence of a state medical futility statute, the Texas Advance Directives Act¹ provides a workable consensus-based template for legal advisors to apply in cases where life-sustaining treatment may be medically ineffective. Legal advisors should also keep in mind that absent a statutory safe harbor provision, state medical futility acts modeled after the Uniform Health Care Decisions Act¹⁰ may not protect against possible civil, criminal or professional sanctions.

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AUTHOR

Mr Sposato is an Attorney-Advisor with the William Beaumont Army Medical Center, Fort Bliss, Texas.



Crest of the William F. Beaumont Army Medical Center,
Fort Bliss, Texas

Biomedical Research Involving Human Subjects

Stephen Maleson, JD

*The history of medical progress is to a large extent the history of medical experimentation.*¹

INTRODUCTION

Clinical Investigation

Human subjects are an integral part of medical research investigation. Testing of a potential drug, device, or vaccine in humans is generally required in order to receive Food and Drug Administration (FDA) licensure. FDA approval and licensure are necessary to make the benefits of the new drug, device, or vaccine available to the general public. Human testing is necessary, in part, because the results of animal testing may not be indicative of how a particular drug, device, or vaccine will perform in a human. Testing in human subjects is conducted as part of a clinical investigation. A clinical investigation is an experiment that involves a test article (drug, device, or vaccine) and one or more human volunteers. A clinical investigation is subject to requirements for submission to the FDA, or the results of which are intended to be submitted as part of an application for a research or marketing permit.²

Substantial Evidence Requirement

Generally, approval of a potential vaccine by the FDA will only occur if clinical investigation reveals that the test article is both safe and efficacious, meaning that a particular test article will work for its intended purpose. A researcher must produce substantial evidence from the clinical investigation that shows that the vaccine (for example) works in humans. The Federal Food, Drug, and Cosmetic Act (FFDCA) defines substantial evidence as

...evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports to have.³

Common Rule

Biomedical research involving human subjects that is conducted or funded by a federal agency is also

regulated by Department of Health and Human Services (HHS) regulations, at 45 CFR 46 (Subpart A) as implemented by the given federal agency. This regulation is known as the “Common Rule,” having been adopted by the Department of Defense (DoD) (at 32 CFR §219) and 15 other federal agencies in 1991. While the FDA regulations and the Common Rule are largely harmonized, investigators must be aware of some differences.⁴ In addition, if a biomedical research project involving human subjects does not involve an FDA-regulated test article and is not conducted to support FDA licensure, the project will not be regulated by the FFDCA and its implementing regulations.

HISTORICAL EVENTS AND ETHICAL PRINCIPLES

The Nuremberg Code: Voluntary Consent

With the exception of highly-regulated emergency research conducted without informed consent, and some minimal risk research, federal regulations prohibit the use of human subjects for research unless the subject’s informed consent or the consent of the subject’s legally authorized representative has been obtained.⁵ These regulations, and others, embody the ethical principles set forth in the Nuremberg Code, the Declaration of Helsinki, and the Belmont Report. The Nuremberg Code is a set of 10 ethical principles that evolved from the trials of the Nazi doctors in 1947.⁶ The key element of the Code focuses on voluntary consent. The Code was derived from international law, international customs, basic humanitarian considerations, and sensitivities of public conscience.⁷ It now represents international common law and is applied in US courts.⁸

The Declaration of Helsinki: Informed Consent and Research Study Review

The *Declaration of Helsinki* was formulated by the World Medical Association in 1964 as a more specific, workable ethical code for medical personnel. The most recent revision of this document occurred in 2008.⁹ Prior to that, it had been revised in 2000, and provisions were clarified in 2002 and 2004. It represents a further evolution of the ethical guidelines to be applied

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by physicians in clinical and nonclinical biomedical research. Like the Nuremberg Code, The Declaration of Helsinki stresses informed consent while adding a requirement for review of the research study.¹⁰

The Belmont Report: Ethical Guidelines for Protection of Human Subjects

The *Belmont Report*¹¹ resulted from study and deliberations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974-1978). The Commission was established by the National Research Act, Pub L 93-348 (1974), to identify the basic ethical principles concerning human subjects that should be applied in the performance of biomedical and behavioral research. The *Belmont Report* sets forth the guidelines that are incorporated into federal regulations for the protection of human subjects. This guidance is applied in the evaluation of research proposals for federal funding.

Other Developments

Other noteworthy actions include the creation of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1980-1983), the Advisory Committee on Human Radiation Experiments (1994), and the National Bioethics Advisory Commission (1996). The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research was created by Pub L 95-622,¹² which required all federal agencies to adopt the Common Rule. The deliberations of the Advisory Committee on Human Radiation Experiments resulted in Executive Order 12975,¹³ which established the National Bioethics Advisory Commission (NBAC) in response to disclosure of human subject abuses in federally supported radiation experiments. The NBAC's primary goal was to develop clear ethical standards for the protection of human subjects during the conduct of research. The NBAC's charter expired in 2001, and, in that same year, President George W. Bush created the President's Council on Bioethics, which is charged with advising "...the President on bioethical issues that may emerge as a consequence of advances in biomedical science and technology."¹⁴

ETHICAL PRINCIPLES OF RESEARCH

The consensus within the research and ethics communities is that all research should be conducted in keeping with 3 basic ethical principles: respect for

persons, beneficence, and justice. These principles are considered to have equal moral force, although their implementation may be expressed differently in different circumstances.

Respect for Persons

Respect for persons includes respect for the autonomy of the individual. Autonomy is essentially the right of self-determination. Thus, researchers should respect an individual's exercise of self-determination in making decisions about his or her body. The *Belmont Report*¹¹ emphasized that researchers must respect the individual by giving weight to his or her informed consent to participate in the study and the weighing of the relative risks and benefits of procedures that will be performed. Respect for persons also acknowledges that vulnerable individuals with diminished autonomy should be protected from harm or abuse. All of the ethical guidelines discussed above focus on autonomy of the subject as a key principle.

Beneficence

The concept of beneficence requires that researchers maximize the potential benefits and minimize potential harms to the subject. In other words, potential risk to the subject must be reasonable in proportion to the anticipated benefits of the research study and the knowledge sought. In addition, the study must be scientifically meritorious, and the researcher must be qualified to conduct the research and competent to protect the subjects from deliberate harm. An individual may choose to participate in a study when death is a probable result. However, the responsibility for the individual must always rest with the medical personnel even though the subject has given consent. Concern for the well being of the individual subject must always outweigh the potential benefit to society as a whole.⁹

Justice

Justice requires the equitable distribution of the benefits and burdens of research among the participants and recipients of the benefits of research. Recruitment of subjects should not be limited to specific categories of persons while the general population reaps the benefits of that group's participation. For example, exclusive use of mentally disabled persons as human subjects because of a perception that they are not socially valuable individuals would be improper. Conducting a study with this group of subjects may be permissible if the study seeks to answer some scientifically valid

question about mental disability. Treating a specific group differently should be based upon some morally relevant justification or meritorious scientific inquiry.

Informed Consent

Risk/Benefit Analysis. Whether to participate in a particular research study is a choice the potential subject must make based on adequate and essential information presented during the process of “informed consent.” Informed consent requires that sufficient information about the conduct of the research and possible benefits or risks to the subject be presented in such a way that the subject can make a reasoned and informed decision about whether to participate in the research. The standard applied in determining whether there has been informed consent is whether there has been disclosure of all information that a reasonable person would consider material in weighing the potential benefits and risks of participation.

Without Coercion. In keeping with the ethical principles discussed above, it is important to stress the voluntary nature of the subject’s participation throughout the informed consent process. The researcher must avoid any action or statement that could be construed as deceptive, applying undue pressure or influence, or seeking to intimidate the potential subject into signing the consent document. The potential subject must be assured of the ability to withdraw from the study at will and without penalty. If payment or other compensation is to be made for participation, such compensation cannot be so enticing as to be coercive or irresistible to the individual.

Documentation. In the general research community, informed consent is usually documented in writing with a signed consent form, but may be obtained orally in certain circumstances.¹⁵ The consent document must address all of the 8 basic elements of informed consent discussed below and may not include any exculpatory language through which subjects are made to waive, or appear to waive, any legal rights they may have. Furthermore, the consent form should be written in nonmedical language that is easily understood by the subject. A translation of the consent form for subjects who do not understand English must also be provided.

Continuing Obligation. It is important to remember that informed consent is a continuous process. The informed consent document is not simply a piece of

paper to be executed at the beginning of a study and then filed and forgotten. The researcher has a continuing obligation to notify the subject of any new information or changed circumstances that may affect his or her participation in the study. The researcher’s obligation continues even after the study has concluded.¹⁶

Selected Elements of Informed Consent

There are 8 basic elements of informed consent set forth in the Common Rule.¹⁷ At a minimum, the 8 elements must become part of the informed consent document, but agencies may impose requirements for additional disclosures to the subject. Researchers must provide a statement to the subject that the study involves research, the purpose of the research, the expected duration of the subject’s participation, an explanation of the procedures to be performed, and identification of any procedures that are experimental. In addition, there must be a description of the reasonably foreseeable risks to the subject due to his or her participation, as well as benefits anticipated, if any. The subject must also be provided with information about alternative procedures or treatments that might be beneficial to him or her. Confidentiality of medical or research records must be addressed, as well as an explanation of compensation to be provided, if any. The subject must also be informed whether medical care and/or compensation will be provided in the case of injury related to the study. Of extreme importance is the requirement that the subject be made aware that his or her participation is voluntary and that he or she may withdraw from the study at any time without suffering penalties or loss of benefits to which the subject is otherwise entitled. Finally, a point of contact must be provided concerning the subject’s participation in the study.

FEDERAL LAW AND DOD REGULATIONS

The body of law governing the use and protection of human subjects in federally funded or conducted research is an amalgam of ethical considerations, international common law, US statutes, and specific regulations promulgated by federal agencies. In 1991, the DoD and 15 other federal agencies adopted HHS regulations at 45 CFR 46 (Subpart A) concerning the protection of human subjects in federal research. As discussed earlier, the adopted regulations are referred to as the Common Rule.¹⁸ The Common Rule applies

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to all research funded by the federal government, whether intramural or extramural, via grants, contracts, cooperative agreements, or cooperative research and development agreements. The Common Rule incorporates the principles discussed in the *Belmont Report*¹¹ and requires institutional assurances of compliance with federal law, the creation of institutional review boards, and informed consent of the subject or the subject's legally authorized representative to participation in the research study.

The HHS also published regulations at 45 CFR 46 Subparts B, C, and D. These Subparts address research activities involving fetuses, pregnant women, and neonates (Subpart B), prisoners (Subpart C), and children (Subpart D). Though these Subparts are not part of the Common Rule, these Subparts are made applicable to DoD research by paragraph 4.4.1. of *Department of Defense Directive 3216.02*.^{19(p3)}

10 USC §980²⁰ is a federal statute that applies only to research funded by the DoD. 10 USC §980 restricts the DoD's ability to conduct or fund certain research that would otherwise be in compliance with the Common Rule. It requires the following for DoD-funded research involving human subjects: (1) the informed consent of the subject must be obtained in advance; and (2) if a subject is unable to legally give informed consent (eg, children, the mentally ill, unconscious persons, trauma victims), the legal representative of the subject may give the informed consent of the subject in advance, but only if the research is "intended to be beneficial" to the subject. The intent-to-benefit requirement of 10 USC §980 creates a challenge in the conduct of certain placebo research involving children that is otherwise approvable under the Common Rule and the HHS Subpart regulating research with children. The impact of 10 USC §980 on research involving children is discussed later in this article.

10 USC §980 has also historically made it difficult to conduct DoD-funded research involving trauma victims and unconscious subjects because it is often impossible to get informed consent from such subjects or their legal representatives in advance. The National Defense Authorization Act of 2002 amended 10 USC §980 to address this issue. The amendment permits the Secretary of Defense to waive the requirement for advance informed consent:

with respect to a specific research project to advance the development of a medical product necessary to the

armed forces if the research project may directly benefit the subject and is carried out in accordance with all other applicable laws.²¹

Paragraph 4.2.2. of *Department of Defense Directive 3216.02*^{19(p3)} (the implementation directive for 10 USC §980), the Secretary of Defense delegated this waiver authority to the heads of DoD components (eg, Secretary of the Army). Other applicable laws include the FDA regulations governing use of investigational drugs or devices in emergency research without informed consent,²² or, for research not regulated by the FDA, the equivalent HHS regulation.²³ The waiver may be requested for DoD research intended to improve treatment of battlefield injuries, using new techniques, drugs, or devices, on a research population that may be difficult to identify and/or obtain informed consent from in advance.

Department of Defense Directive 3216.02 also creates certain DoD-unique obligations for research involving human subjects conducted or supported by the DoD (eg, through contract, grant, cooperative agreement, or other arrangement). For example, paragraph 4.4.3 states:

For research involving more than minimal risk to subjects (as defined in 32 CFR 219.102(i)), an independent medical monitor shall be appointed by name. Medical monitors shall be physicians, dentists, psychologists, nurses, or other healthcare providers capable of overseeing the progress of research protocols, especially issues of individual subject/patient management and safety. Medical monitors shall be independent of the investigative team and shall possess sufficient educational and professional experience to serve as the subject/patient advocate.^{19(p4)}

Additionally, paragraph 4.4.3.2. gives medical monitors

...the authority to stop a research study in progress, remove individual subjects from a study, and take whatever steps are necessary to protect the safety and well-being of research subjects until the IRB [institutional review board] can assess the medical monitor's report.^{19(p4)}

Multiple Army regulations may also affect research involving human subjects. *Army Regulation 70-25*¹⁶ applies to Army RDT&E* research involving human subjects. *Army Regulation 40-38*²⁴ applies to the research involving human subjects in the Clinical

*Research, development, test and evaluation

Investigation Program. Both of those Army regulations further govern the Army's research involving human subjects. If Army research involves FDA-regulated products, the conduct of such research is also governed by *Army Regulation 40-7*.²⁵

Institutional review boards (IRBs) are charged with protecting the rights and welfare of human subjects and to ensure that accepted ethical principles are applied in the conduct of research upon humans. The IRBs do this primarily by reviewing research plans (protocols) and serving as biomedical research ethics advisory boards. All Army research studies must be reviewed by an IRB whether the research conducted is intramural or extramural. All protocols must be reviewed prior to beginning the research. Extramural research protocols will usually be reviewed by the institution conducting the research. In the DoD, extramural research and intramural research that is greater than minimal risk must also receive a "headquarters-level" administrative review. This additional review requirement is unique to the DoD, and arises from paragraph 5.3.3. of *Department of Defense Directive 3216.02*.^{19(pp6-7)}

Laboratory commanders at the US Army Medical Research and Materiel Command (USAMRMC) have the authority, after IRB approval, to approve minimal risk research. The Commanding General (CG), USAMRMC, has the authority to approve the use of human subjects in other research studies. The Human Subjects Research Review Board (HSRRB) serves under the CG's authority. The HSRRB functions as an IRB for certain categories of research, and performs the headquarters-level review function for other research, which must first have been reviewed and approved by an IRB. The HSRRB has authority to recommend CG approval of research, and may also disapprove, or defer approval of the protocol. It may also recommend approval of the submitted protocol conditionally, requiring modifications or extra protections. In addition, the HSRRB may suspend or terminate an ongoing study. For research within the Clinical Investigation Program, the Clinical Investigation Regulatory Office (CIRO), recently relocated under the USAMRMC, provides the headquarters-level second review. For research, development, test, and evaluation (RDTE) work for which the HSRRB serves as the IRB, the Army Human Research Protections Office provides headquarters-level review.

An institution conducting research must first determine if an activity in question is "research involving human subjects" under the Common Rule, as the Common Rule and its requirement for IRB review do not apply to activities that do not meet that definition. In addition, even if a given activity is determined to be research involving human subjects, the research may be exempt from the Common Rule, and therefore exempt from IRB review. A commonly cited exemption is research involving the collection or study of existing data, documents, records, or specimens, if sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified. The determinations of applicability of the Common Rule and/or exemption of research from the Common Rule can be made by the institution in whatever manner it deems appropriate. However, if there is even a possibility that a given activity may be nonexempt research involving human subjects, it is advisable to involve the IRB or the institutional office with human subjects protection expertise in both determinations.

One of the tasks of the IRB is to determine the level of risk of the research. The risk levels are minimal risk and greater than minimal risk. The Common Rule defines minimal risk as the level of risk in which probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. An analysis of risk should include any risks unique to the study and an estimation of their severity and likelihood of occurrence. The risks presented in the protocol should be compared with risks the subject might encounter in the course of his or her daily activities. The risk level is relevant because it may affect the IRB and headquarters-level review processes; a medical monitor is not required for minimal risk research, and certain minimal risk research can be conducted with a waiver of informed consent.

In addition to reviewing the informed consent document, the IRB, CIRO, and the HSRRB will also review the entire protocol to ensure that the risks to the subjects are minimized and in proportion to the importance of the knowledge to be gained. Selection of subjects will also be reviewed to confirm that the pool of subjects is equitable. Recruitment documents and advertisements will be reviewed to ensure that the

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study is not misrepresented to potential volunteers. Although the IRB and headquarters-level review do not include an independent scientific review, the reviews do consider scientific merit in the risk-benefit analysis.

SPECIAL ISSUES

Women and Minorities

The FDA and the National Institutes of Health (NIH) guidance encourages diversification in clinical trials unless there is a scientific reason for excluding a certain category of human subjects.²⁶ The FDA has stated that subjects included in clinical studies should, in general, reflect the population that will receive the drug when it is licensed and marketed. Representatives of both genders should be included in clinical trials in numbers adequate to allow detection of clinically significant gender-related differences in drug responses. It is the policy of NIH that women and members of minority groups must be included in all NIH-funded research, unless a clear and compelling rationale and justification establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of child-bearing potential should not be routinely excluded from participation in clinical research.²⁷ Similarly, inclusion of minorities in research studies is needed to obtain valid analyses of whether test variables affect members of minority groups differently. With the passage of the National Defense Authorization Act for Fiscal Year 1994,²⁸ the DoD adopted the essential elements of the NIH guidance. The DoD now requires the inclusion of women and minorities in DoD funded or conducted research.

Vulnerable Populations

Certain categories of study subjects, such as children, incompetents, and prisoners, constitute "vulnerable" populations for whom special protections are warranted. As a general principle, research studies should use subjects that are considered less vulnerable before recruiting more vulnerable populations for participation, unless the research is specifically intended to benefit the vulnerable population being recruited, and the vulnerable population must be involved in order for the research to be successfully conducted.

Children and Incompetents

As previously mentioned, research directed at a specific category of subjects must seek to answer a specific scientific question pertaining to that group. For instance, children would be appropriate subjects for research on infectious diseases that afflict mostly children. The DoD, through *Department of Defense Directive 3216.02*,¹⁹ requires compliance with HHS regulation 45 CFR 46, Subpart D (Additional Protections for Children Involved as Subjects in Research). This regulation specifies that the minor's assent (in addition to the parent or legal representative's consent) should generally be obtained if the minor is capable of understanding the object of the research study and the procedures to be performed.

As an additional protection for minors and incompetents, DoD researchers are bound by the provisions of 10 USC §980, discussed above. This law states, in relevant part:

Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless ... in the case of research intended to be beneficial to the subject, the informed consent of the subject or a legal representative of the subject is obtained in advance.²⁰

Because research involving children requires the consent of the child's legal representative, as opposed to consent of the child, who cannot legally consent, the research must intend to benefit the child. Certain research that does not intend to benefit each minor subject would be approvable under the HHS subpart D, in the absence of 10 USC §980.

The required intent to benefit of 10 USC §980 can be met if (1) the test article, drug, vaccine, or device is intended to benefit subjects who receive it; or (2) there are other intended benefits to subjects from the research, such as medical diagnostic testing, health care given during the research, psychological counseling, or nutritional analysis. There must be an intended benefit for each individual subject. It is not necessary for each subject to receive the same benefit, and it is permissible for some subjects to benefit more than others.* The IRB that is reviewing the research is the appropriate body for determining whether there is an intended benefit, and whether that intended benefit is sufficient. An intended benefit must at a minimum be a

*Memorandum from MAJ Dale Woodling, Office of The Judge Advocate General, US Army, dated September 1, 1998. Available at the Office of the Staff Judge Advocate, US Army Medical Research and Materiel Command, Fort Detrick, MD.

medical benefit, as differentiated from compensation that may be provided to research subjects. 10 USC §980 has made it challenging, though not impossible, to conduct certain placebo research involving children, because investigators must demonstrate that such research intends to benefit each subject, including those who receive the placebo.

Prisoners

Although there is no per se prohibition on the use of prisoners as human subjects, studies proposing to use prisoners are controversial and should be carefully reviewed. DoD has conducted some research involving prisoners, and specifically adopted Subpart C of the HHS regulations which governs research involving prisoners. However, prisoners of war will not be used as research subjects.^{19(p3)} Although prisoner populations may be very attractive to researchers because of their standardized living environment and availability for long-term studies, those populations may be susceptible to coercion or unstated pressures to volunteer or continue in a research study.

Soldiers as Subjects

Soldiers may also be considered a vulnerable population because of the special command authority and restrictions on autonomy imposed by the military environment. Soldiers may have the misperception that they will receive preferential treatment, good performance reports, or other benefits if they volunteer to serve as subjects. Alternatively, they may volunteer because they fear disapproval or retaliation for failure to participate in a command sponsored study. However, participation in any study must be truly voluntary and there are no Uniform Code of Military Justice²⁸ or administrative actions for declining to participate in or withdrawing from a study. Recognizing the influences of the military command structure, paragraph 4.4.4. of *Department of Defense Directive 3216.02*, generally prohibits presence of officers and noncommissioned officers at group recruitment briefings of Soldiers under their command. Furthermore, provision for a disinterested ombudsman may be required to monitor group recruitment of service members to ensure that the voluntary nature of participation is stressed.^{19(p4)}

Others Who Require Special Protection

Other groups face similar pressures or misconceptions concerning participation in clinical studies supported

or conducted by their organizations. For example, medical and nursing students may feel pressure to volunteer for studies conducted by their teaching hospitals. Persons with advanced terminal diseases may be more vulnerable to recruitment for riskier protocols as a “last hope.” Indigents as a group also require special protection as they may have weakened physical and mental conditions, economic disadvantage, and generally, lack any family or community support in decision-making.

Medical Care

With regard to medical care for research-related injuries, the Common Rule merely requires subjects to be informed if medical care is available, and what costs may be involved. Such medical care, if available, may be billed to the subjects or subjects’ insurance and need not be provided free of charge.³⁰ However, pursuant to paragraph 5.3.4. of *Department of Defense Directive 3216.02*,^{19(p7)} DoD components must “protect human subjects from medical expenses (not otherwise provided or reimbursed)” that are for treatment of research-related injuries from research for which primary involvement is from the DoD.

Given the lesser requirement of the Common Rule and the inability of the federal government under fiscal law principles to commit to paying indefinite medical care costs, this provision has created some conflict with extramural research partners. It has also created some uncertainty within the DoD for components conducting intramural research involving human subjects who are not DoD health care beneficiaries.

The DoD components interpret and address this provision in different ways. For example, the USAMRMC instructs extramural partners to include, after their own Common Rule policy, language in their consent forms informing subjects of the availability of no-cost medical care at Army medical treatment facilities, in accordance with *Army Regulation 70-25*¹⁶ and paragraph 3-56 of *Army Regulation 40-400*,³¹ and of a process to seek reimbursement (nonguaranteed) for out-of-pocket, research-related medical expenses incurred. Other DoD component mechanisms for attempting to meet this requirement include limiting enrollment to subjects who are DoD healthcare beneficiaries, and/or seeking DoD component Secretary designee status on an ad hoc or categorical basis for injured subjects who are otherwise not entitled to DoD healthcare.

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COMPENSATION RELATED TO PARTICIPATION

It is permissible for research subjects to receive payments or other compensation for participating in a study. Acceptable compensation includes, but is not limited to, reimbursement for transportation costs, other minor or incidental expenses, inconvenience associated with participation, and blood draws. Unacceptable compensation would be that which seems excessive, unwarranted, or appears to be an improper reward to obtain compliance. Compensation that would normally be acceptable may become an unacceptable inducement for a particular person or vulnerable group. Individual situations and cultural considerations must be evaluated in determining whether a particular payment is an improper inducement to participation or at what point a payment might become an improper inducement.

Ability to compensate military service members for research participation has been a source of confusion. A federal law, 24 USC §30 (2002), permits compensation for blood draws, not to exceed \$50 per blood draw, to be paid to "on-duty" service members (ie, when the service member is not on leave, and is participating during his or her duty hours). A service member who is participating while on-duty may only be compensated for blood draws, and may not be otherwise compensated for research participation. By permitting compensation for blood draws while on-duty, 24 USC §30 provides an exception to another federal law, the Dual Compensation Act of 1964,³² which prohibits service members from being paid by any source other than their regular military salaries while they are on duty.

"Off-duty" service members (service members on leave, or participating after his/her duty hours) may be compensated in the same manner as nonmilitary research subjects. Off-duty service members therefore may be paid more than \$50 per blood draw and may be compensated for research participation generally (not only for blood draws). However, payment to off-duty service members for research participation other than blood draws must not be directly from a federal source (payment from a contractor or other nonfederal source is permissible). In addition, within the Clinical Investigation Program as regulated by *Army Regulation 40-38*, compensation of off-duty service members may still be limited to \$50 per blood draw,

with no distinction drawn between on duty and off-duty participants for the purpose of compensation.^{24(p7)}

Service members should get command permission to participate in research while off-duty. Participation in off-duty research may affect a service member's ability to perform his or her military duties. Principal investigators should confirm that a service member's commander supports the service member's research participation.

SPECIMEN DONATION

If blood, tissue, or body product samples will be drawn during the study, the subject should be informed as to the procedures by which the specimen will be obtained, the amount of tissue or fluid withdrawn, and its use. Withdrawal of blood, for example, should be described in lay terms such as "two teaspoons worth." If specimens will be obtained in the study for possible future use in another protocol, the informed consent document should include a statement notifying the subject of this possibility, and providing an option to permit or forbid such use. The consent document should also notify the subject that the specimen could potentially have some commercial applicability, but also include language that explicitly donates the specimen to the federal government and relinquishes all right, title, and interest in the specimen.

CONFIDENTIALITY AND RECORDKEEPING

Records pertaining to the use of volunteer subjects should include a copy of approved consent documents, a copy of the approved research protocol, minutes of the IRB review, the commander's recommendations, a summary of the research results including any adverse event reporting, and records compiled for the volunteer database. In addition, there will often be identifiable medical information related to the subject, either from a subject's existing medical records, or created by the subject's participation in research .

For intramural RDTE research involving greater than minimal risk, and some other research projects, information about research subjects is entered into a volunteer registry database. The database contains personal information about the individual such that a subject's questions about his or her participation in a particular research study can be answered. In addition, the database is necessary to ensure that the research organ-

ization can comply with its obligation to adequately warn volunteers of risks and to provide relevant new information as it becomes available. A statement must be included in the consent form for research as to which information will be entered into the database, notifying the subject that personal information will be collected, the purpose for collection, and duration of time the information will be maintained in the database. The subject must also be notified that representatives of the DoD and FDA (if research is regulated by the FDA) may inspect the records of the research in fulfilling their duty to protect human subjects.

The extent to which records will be kept confidential must also be addressed. If the subject is a Soldier, notice must be given that complete confidentiality cannot be guaranteed, as certain medical conditions must be reported to the Soldier's commander or others. Any system of records must comply with *Army Regulation 340-21*,³³ the Army Privacy Program, and the Privacy Act of 1974.³⁴

In addition, the Health Insurance Portability and Accountability Act³⁵ (HIPAA) Privacy Rule regulates the use and disclosure of individually identifiable health information, and in the context of research this generally requires an "authorization" to use and/or disclose such information. The authorization can be integrated into or separate from the consent form. The DoD regulation that implements HIPAA is *Department of Defense 6025.18-R*.³⁶ *Army Regulation 40-66*³⁷ also discusses HIPAA.

LIABILITY ISSUES

Feres Doctrine

The *Feres* case generally precludes successful suits by service members for personal injury or death that is incurred incident to service.³⁸ Medical malpractice cases are generally dismissed because medical care in military facilities is considered incident to service, even if the treatment or surgery was elective. A suit brought for personal injury or death resulting from participation in a research study would have certain similarities to a medical malpractice case and would most likely be barred if brought by a service member.

Tort Litigation

Suits arising from participation in DoD-conducted research studies would most likely be filed pursuant to The Federal Tort Claims Act (FTCA) which waives

sovereign immunity to suit in certain limited cases.³⁹ The FTCA does not prohibit suits for injury or death resulting from the negligence of government employees in conducting the research study. However, a plaintiff would have to prove that his or her injury is the proximate result of participation in the study and that some duty had been violated. Litigation would most likely concern issues of informed consent and the adequacy of the informed consent document. Specifically, allegations might assert inadequate disclosure of risks of personal injury or death. Causes of action may also be asserted that research or commercial interest in specimens was not disclosed or that the investigator was influenced in his treatment of the subject by a conflict of interest. There might also be claims resulting from the personal injury or death itself. Although the informed consent document may generate litigation, if drafted properly the document may serve as written evidence that the subject was warned of and acknowledged the risks associated with his or her participation in the study.

Cobbs v Grant,⁴⁰ a California medical malpractice case, discussed the evolution of the negligence theory for inadequate disclosure and failure to obtain informed consent. Legal analysis in previous cases employed a battery theory instead of a negligence theory. The *Cobbs* court concluded that a battery theory should apply only when the procedure implemented is substantially different from the procedure consented to. The court also stated that inadequate disclosure of risks is really a question of the standard of professional conduct. The "patient's dependence upon and trust in his physician for the information upon which he relies during the decisional process raises an obligation in the physician that transcends arms-length transactions." The court held that an integral part of the physician's obligation to the patient is a duty of reasonable disclosure of the available choices with respect to proposed therapy and of the dangers inherently and potentially involved in each alternative. Recognizing the difficulty of defining "reasonable," the court went on to state that the scope of a physician's communication to the patient must be measured by the patient's need, and that need is whatever information is material to the decision. Therefore, the test for determining whether a risk must be disclosed is its materiality to the patient's decision.

The standard of disclosure was also addressed in *Karp v Cooley*,⁴¹ a Texas medical malpractice case involv-

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ing an experimental heart pump. The plaintiff alleged lack of informed consent because the number of animals in which the device was tested and the results of those tests were not disclosed. The plaintiff also claimed that the risk of injury by the mechanical heart and its experimental nature was never disclosed. The court stated that the standard of disclosure was what a reasonable practitioner of the same school of practice and the same or similar locality would have advised a patient under similar circumstances. The court also stated that

Physicians and surgeons have a duty to make a reasonable disclosure to a patient of risks that are incident to medical diagnosis and treatment... True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each.

Failure to disclose research or commercial interest in specimens or investigator conflicts of interest is another area ripe for litigation. In *Moore v The Regents of the University of California et al.*,⁴² the plaintiff's cells were extracted and used to create a cell line with potentially lucrative commercial applications. The plaintiff was never told that his cells were being extracted for any purpose other than treatment; neither was he told that there might be some economic interest associated with the use of his cells. The court stated that a reasonable person would want to know whether his physician has an economic interest that might affect the physician's professional judgment. The court held that the plaintiff was not required to prove that his cells had potential commercial value at the time they were extracted. The court also held that

...a physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment.

Failure to disclose such interests would give rise to a cause of action for negligence.

CONCLUSION

Use of human subjects in research poses unique ethical questions that become more perplexing as biomedical technology increases in complexity and sophistication. The amalgam of ethical considerations, international common law, statutes and regulations protecting

volunteer subjects is also becoming more complex. Scientists must seek to understand the necessity for enforcing protections for human subjects while devising new ways to solve scientific conundrums. Ethicists must endeavor to understand the importance of research in advancing knowledge. Regulators must be conscious of the shared objectives and competing concerns of both groups. A balancing of all interests must continue for successful development of new therapeutic drugs, devices and preventative vaccines for the benefit of all.

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AUTHOR

Mr Maleson is an Attorney Advisor with the Office of the Staff Judge Advocate, US Army Medical Research and Materiel Command, Fort Detrick, Maryland.



The Medical Affirmative Claims Program

Melissa W. Hartley, JD

INTRODUCTION

The Medical Affirmative Claims (MAC) Program is an excellent source of revenue for the medical facility for costs incurred due to care rendered to a Department of Defense (DoD) beneficiary who was injured as the result of a third party. The MAC program collects the cost of care arising from care rendered at the military treatment facility (MTF), from TRICARE* liens, and from lost wages of service members who were unable to fulfill government duties due to their injuries. This program is administered by local legal offices, under the jurisdiction of the US Army Claims Service (USARCS) and is described in detail in *Army Regulation 27-20*.¹

This article describes the applicable laws, jurisdiction, and mechanics of the MAC program at the MTF level. For more in-depth information on specific case issues, the higher headquarters for technical oversight is USARCS at Fort Meade, Maryland. Reporting MAC claims can be done at the MTF's servicing legal office or, if at a smaller medical facility, at the servicing consolidated legal office.

APPLICABLE LAWS

Recovery Sources. The MAC program is primarily based on the Federal Medical Care Recovery Act (FMCRA)² which was originally enacted in 1962. The FMCRA specifically covers tort-feasor liability. (A tort-feasor is a person causing injury or legal harm to another.) The program has been expanded through case law to also include 10 USC §1095³ which allows recovery from "no fault" insurance. 10 USC §1095 is also the basis for the Third Party Collections Program to bill other health insurance. However, its application within the MAC program is to allow billing of medical care to "no fault" forms of insurance or other applicable coverage.

Statutes of Limitation. 28 USC §2415 (2002) summarizes the applicable statutes of limitation

(SOL). FMCRA third party liability SOL is 3 years. However, when dealing with "no fault" provisions of insurance such as personal injury protection or uninsured motorists, the SOL may be extended to 6 years. State laws also overlap somewhat into the MAC program. Actions asserted on a third party beneficiary basis against an insurer or against state labor and industries cases must comply with the applicable state law SOL in order to receive payment. In many cases, this can be as little as one year. Therefore it is imperative that MAC cases be reported to the servicing legal office as soon as they are known by the medical provider.

Subrogation and Attorney's Fees. Attorney's fees or subrogation provisions arising in state law do not apply to the MAC program. FMCRA gives the government a "separate statutory right of action," and the government is not bound by the signature or settlement of the claimant in any way. Any payment to the patient by the insurance company does not extinguish the government's lien or independent right of action. Therefore, notice of a MAC claim should always be asserted directly to the insurance company or other source of payment, as well as to the patient's attorney. Additionally, state law provisions of pro rata sharing of patient's attorneys fees are also inapplicable to the federal government's lien.⁴

JURISDICTION

Exclusions. The jurisdiction of the MAC program is specifically for all DoD beneficiaries when they are injured by a nonfederal source. This includes active duty personnel, retirees, and all dependants. Bills for civilian emergency care, Veteran's Administration patients, and intra-agency patients are billed by the hospital treasurer and are outside the scope of FMCRA. The tort-feasor who caused the injury to the DoD beneficiary must be a nonfederal source. A Soldier, retiree, or family member injured by another person's personally owned vehicle is asserted as a MAC claim. A Soldier injured by a military convoy

*TRICARE is DoD's healthcare program for members of the uniformed services, their families, and their survivors. Information available at <http://www.tricare.mil>.

would generally not be asserted. Likewise, a premises liability case would depend on the status of the building where the injury occurred.

Dollar Amount Jurisdiction. Dollar amount also affects jurisdiction for decisions on cases. Jurisdiction of cases at the local MAC office includes any case under \$50,000. Any case with the potential to incur costs in excess of \$50,000 is outside of local authority and must be coordinated with the USARCS. A mirror file of the entire case, along with a memorandum of recommendations must be forwarded to USARCS. Cases that are expected to exceed \$100,000 should be sent to USARCS but the Department of Justice will have decision authority on all compromise and waiver requests stemming from that claim. All cases should be reported to the local servicing consolidated legal office, and will then be processed accordingly.

Service Affiliation. Service affiliation can also affect the jurisdiction of a claim. Generally, Army beneficiary cases will be asserted by the MTF but other service beneficiaries will be billed and transferred to the servicing legal office for their branch of service. Jurisdictional lines of many cases may currently be affected by realignment of some clinics by local BRAC* agreements. Jurisdiction of a case can also be worked out with the other service or MTF on a case-by-case basis based on the location of attorneys, witnesses, and where the majority of care occurred. Often, Army MAC offices may also negotiate transfer of a case within the Army when one MTF has the majority of medical care or liens. Upon settlement, money is divided into pro rata shares to all MTF accounts or TRICARE, based on where the actual care is rendered. However, the patient or patient's attorney has one primary point of contact to deal with throughout the FMCRA process.

MECHANICS OF THE PROGRAM

Identification of Claims. The identification of MAC cases takes work and communication between a legal office and the MTF staff. Cases can be identified through the coding of the patient encounter or reported by clinic staff based on the patient's medical history given at the time of the visit. Reporting MAC cases to the servicing legal office is within the allowable exceptions for release under applicable HIPAA laws.^{5,6}

Military police blotters and civilian newspapers are good sources for recovery of TRICARE cases. Legal correspondence from outside sources can also help to identify MAC claims. The request from the patient's attorney for records from the patient administration division (PAD) office should be held until the MAC office is given notice. In many cases, the MAC office can assert bills along with the records request so that an insurance settlement is not made before the government's lien is asserted. Requests to the MTF legal office for medical witness testimony are often a sure sign of litigation in a MAC claim.

INDIVIDUAL CASE SCENARIOS

Motor Vehicle Accidents (MVA). The bulk of MAC cases are motor vehicle accidents which are usually tort liability cases asserted against the third party tortfeasor's insurance policy.² This is often a patient who has been hit by another driver, but may be a patient who was a passenger in another person's vehicle. Recovery sources can also be found with patients injured in their own car while another family member was driving or with policies of the owner of a "borrowed" car. The patient's own policy may have a separate pedestrian clause or other provision covering him or her if he or she is injured in the roadway or parking lot.³ The third party liability carrier is generally the largest source of recovery, but will also generally take the longest to settle and pay the MTF. Assertion should be made to all insurance carriers because the patient's own car insurance may have medical payment or personal injury protection provisions that will pay immediately. This payment source is generally exhausted quickly by civilian providers such as chiropractors or other care providers not generally covered by TRICARE. Products liability issues with tires or brakes, negligent highway barrier design, and other types of recovery are often available to the plaintiff.

Premises/Product Liability. Other types of MAC cases arise from premises or product liability. Premises liability cases are usually "slip and falls" and are asserted against the building owner's insurance. In order to assert a MAC claim, the building must be owned by a nonfederal source. Buildings owned by state government are a source of MAC claim covered by the FMCRA, but no federal buildings of any kind are covered. Products liability cases are generally

*Base Closure and Realignment Committee – The congressionally authorized process for DoD to reorganize its base structure to more efficiently and effectively support forces, increase operational readiness, and facilitate new ways of doing business. Information available at: <http://www.defenselink.mil/brac/faqs001.html>

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recoverable unless it involves a military source. Many product liability cases involve injuries by toys, so pediatric and family practice physicians should be informed of toy recalls and of the MAC claims reporting mechanism utilized by the MTF. Recoverable injuries seen in MAC programs include injuries caused by such things as small parts, lead exposure in paint, magnets, and detachable buttons or small pieces on baby clothing. Other possible claims involving incidents such as food poisoning, dog bites, and mold exposure should also be identified and asserted.

Worker's Compensation. State worker's compensation cases are determined by the status of the employer. A MAC claim may be asserted under 10 USC §1095³ in the instance of an active duty service member injured while engaged in off-duty employment off post. Remember to look at the status of the off-duty employer, not of the patient. A MAC claim can be asserted if the employer is a private entity or a state government agency. If the employer is another federal source, a MAC claim would not be asserted. Retiree injuries may be recoverable as a MAC claim if their second career is with an employer other than a federal agency. Federal employee cases are not asserted.

Medical Malpractice. Medical malpractice claims from nonfederal sources may also be recoverable. A MAC claim can be asserted if the patient is transferred to an MTF for a lengthy recovery process from prior malpractice, or if TRICARE expends coverage for revision surgery or other necessary followup. Recovery can be obtained through the patient's civil litigation attorney or be asserted directly to the civilian hospital's insurance carrier. Many of these cases are transferred from a civilian hospital via ambulance directly to the MTF surgical service, so efforts should be made to have MTF surgeons or medical staff report the case directly to the MAC office when the patient is received by the MTF.

Criminal Restitution. Restitution cases come from a variety of sources. MAC cases are often identified by subpoenas. The civilian prosecutor's office routinely sends subpoenas to the MTF for medical witness testimony.⁷ If the care was rendered to a DoD beneficiary, the legal office can request restitution upon sentencing of the criminal defendant. These cases can be identified by requests to the PAD office for emergency room records or by law enforcement

requests for records. In any criminal case, restitution claims can be submitted to the witness liaison or the prosecutor, and restitution can be ordered by the courts. Additionally, many states have specific laws for victims' compensation programs that may offer additional "no fault" sources of recovery even if a criminal defendant is never actually charged. These would be state crime victims' funds and differ depending on individual state law.

PROCESSING THE CLAIM

Assertion and Collection. Exact procedures for assertion and collection are outlined in *Army Regulation 27-20*.¹ Timing is the key to successful recovery of funds for any MTF. Early identification of MAC claims and assertion to all available sources of recovery is a must. Timely updates for ongoing medical care and frequent contact by the legal office with plaintiff's attorney or the recovery source is necessary to insure that a case is not settled without the government's knowledge. MTFs can assist in the MAC recovery process by identifying and reporting claims, and providing timely responses to labor and industries forms requests or civil subpoenas, when coordinated by the servicing legal office.

Waiver and Compromise. In cases of extreme hardship to the patient or when there are limited recovery sources, requests for compromise and waiver of the claim can be processed. The Regional Claims Settlement Officer (RCSO) for the servicing MAC office will process the request to ensure fairness to our DoD beneficiaries in instances when recovery funds are limited.¹ The RCSO has jurisdiction to decide requests for compromise or waiver of the government's interest, if the case is less than \$50,000. Larger cases must be processed by USARCS and those over \$100,000 require approval of the Department of Justice. Numerous factors go into the decision process, including residual injuries of the patient, continued care at government expense, amount of recovery available, and any hardship circumstances of the patient.

CONCLUSION

The Medical Affirmative Claims Program is an excellent opportunity to bring money to the Army military treatment facility. This money is deposited into the operation and maintenance fund of the MTF where the care was rendered. TRICARE also

contributes a percentage of TRICARE funds collected by the MAC office to the MTF through a new cooperative agreement. The money brought to the MTF enhances patient care and is also used for training and equipment for its staff. If your MTF does not have a strong MAC program, consultation with your servicing legal office or the MAC area action officer at the US Army Claims Service is highly encouraged.

4. 5 USC §3106 (2009).
5. *Department of Defense 6025.18-R: Health Information and Privacy Regulation*. Washington, DC: US Dept of Defense; January 24, 2003.
6. 45 CFR 164.512 (2004).
7. *Army Regulation 27-40: Litigation*. Washington, DC: US Dept of the Army; September 19, 1994.

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1. *Army Regulation 27-20: Claims*. Washington, DC: US Dept of the Army; February 8, 2008.
2. Federal Medical Care Recovery Act, 42 USC §2651-2653 (2008).
3. 10 USC §1095 (2009).

AUTHOR

Ms Hartley is Deputy Center Judge Advocate, Madigan Army Medical Center, Tacoma, Washington, and the Regional Claims Settlement Officer for the Western Regional Medical Command.



Crest of the Madigan Army Medical Center,
Fort Lewis, Washington

Adverse Privileging Actions in the Army Medical Department

Rosalind D. Gagliano, RN, JD, LLM

ABSTRACT

Fully 23 years after enactment of the Health Care Quality Improvement Act and 19 years after initiation of the National Practitioner Data Bank reporting requirements, the identification and proper processing of adverse privileging actions continues to be a dynamic, challenging, and rights-preserving system at the forefront of the quality assurance initiatives, both within and outside of the Department of Defense. This article addresses the more pressing legal and practical implications of compliance in the adverse clinical privileging actions forum from the Army Medical Department military treatment facility command perspective.

Adverse Privileging Action

Denying, suspending, restricting, reducing, or revocation of clinical privileges based upon misconduct, professional impairment, or lack of professional competence. The termination of professional staff appointment based upon conduct incompatible with continued professional staff membership may also result in an adverse privileging action.^{1(p8)}

INTRODUCTION

In 1986, the US Congress determined that the increase in occurrence of medical malpractice was a nationwide problem, due in part to the fact that incompetent healthcare practitioners were free to move from state to state without discovery or disclosure of previous actions or censures.² Congress further determined that effective peer review could help remedy the healthcare quality problem, but that the threat of liability served to deter physicians and dentists from participating in peer review. Based upon these premises, Congress enacted the Health Care Quality Improvement Act of 1986 (HCQIA),³ a well-meaning attempt to improve the quality of health care in America. In addition to providing certain limitations on liability for healthcare entities and professionals involved in the peer review process, HCQIA provided for the establishment of a national repository of information pertaining to licensing board sanctions, medical malpractice payments, and adverse privileging actions involving physicians, dentists, and other privileged healthcare practitioners.⁴

This reporting system came to be known as the National Practitioner Data Bank (NPDB). The Health Care Quality Improvement Act's reporting

requirements and the potential availability, real and perceived, of the information contained in the NPDB generated legitimate concern among healthcare entities and professionals nationwide. Indeed, the reporting requirements now significantly affect the way hospitals and medical staffs manage the credentialing, privileging, and peer review processes.

LEGAL AUTHORITIES APPLICABLE TO THE ARMY MEDICAL DEPARTMENT

In addition to HCQIA accountability and reporting requirements, other guidelines applicable to adverse privileging in the AMEDD include the following, without limitation: 10 USC §1102 (governs treatment of information derived from quality assurance processes, including adverse privileging actions); The Joint Commission* guidelines (the Department of Defense (DoD) has mandated accreditation by The Joint Commission for all MTFs); *Department of Defense* [regulation] 6025.13-R,¹ (opt-in to HCQIA, NPDB, and quality assurance processes); *Army Regulation 40-68*⁵ (the Army regulation pursuant to above authorities); and individual MTF policies (local policy consistent with above authorities, such as committee structure and available privileges). Publication of a DoD manual to replace *Department of Defense 6025.13-R* is pending at this writing. The new DoD manual will describe the process and management of clinical adverse actions for privileged and nonprivileged healthcare providers and will apply

*The Joint Commission (One Renaissance Blvd, Oakbrook Terrace, Illinois 60181) is a private sector, US-based, not-for-profit organization founded in 1951. The Joint Commission operates accreditation programs for a fee to subscriber hospitals and other healthcare organizations.

to all MTFs in the Military Health System. In-depth discussion of HCQIA, 10 USC §1102, The Joint Commission accreditation requirements, and local MTF policies are beyond the scope of this article.

CLINICAL PRIVILEGES

Clinical Privileges define the scope and limits of practice for individual providers, and are based on the capability of the MTF and the credentials of the provider.^{1(p8)} A provider's credentials include licensure, relevant training and experience, current competence, health status, judgment, and peer and department head recommendations.^{5(p45)} The process of clinical privileging is the responsibility of the MTF commander, is usually discharged by the MTF credentials committee, and results in the grant of permission and responsibility to a healthcare provider to deliver specified or delineated healthcare within the scope of his or her license, certification, or registration in the MTF.^{1(p8),5(p26)} AMEDD providers must apply for clinical privileges at the receiving MTF each time they transfer, and must apply for renewal every 2 years. Every application for privileges or renewal of privileges triggers a requirement for the MTF to query the NPDB on the particular provider. NPDB information received by the querying MTF is not intended to be expositive of the competency or qualifications of a practitioner, but to serve as a flagging or alert system to supplement existing programs for reviewing the qualifications of practitioners.⁶ The NPDB querying and reporting requirements apply to all healthcare entities, licensing agencies, and some healthcare societies in the United States. The wide-scale application is necessary to fulfill the Congressional intent of preventing incompetent or dangerous providers from freely moving to a different state or hospital, or continuing to endanger patient safety by moving from federal service to the private sector or vice-versa. In the AMEDD, any action by the privileging authority (MTF commander) to deny, suspend, restrict, reduce, or revoke privileges, based on the provider's misconduct, impairment, or lack of professional competence is termed an adverse privileging action.^{1(p8)}

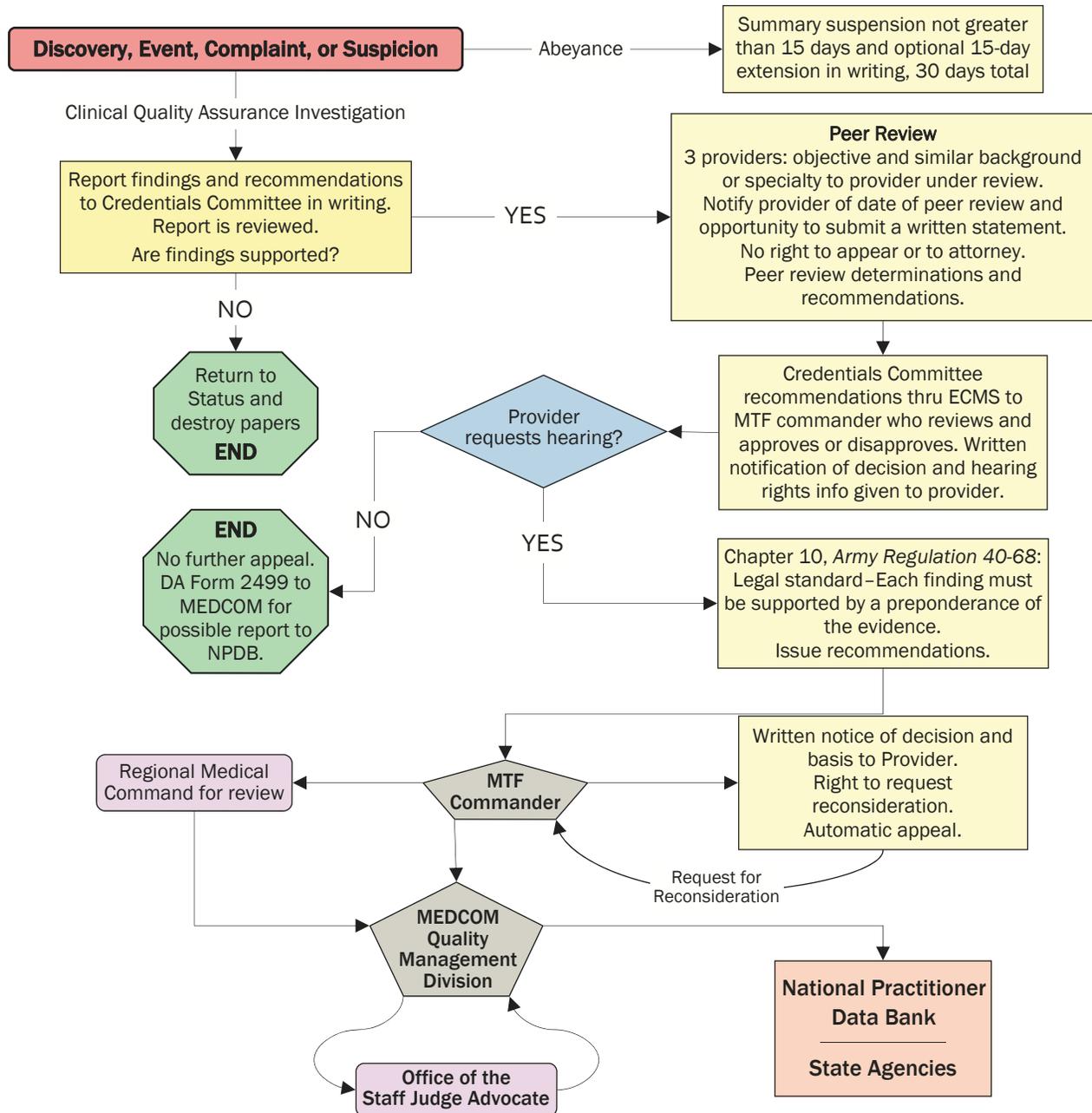
ADVERSE PRIVILEGING ACTIONS PROCESS

The AMEDD adverse privileging process delineated in chapter 10 of *Army Regulation 40-68*^{5(pp71-93)} is summarized in the Figure. Documents and testimony in connection with an adverse privileging action constitutes quality assurance information and,

therefore, subject to the protections and prohibitions in 10 USC §1102, chapter 2 of *Department of Defense* [regulation] *6025.13-R*,^{1(pp21-23)} and Appendix B of *Army Regulation 40-68*.^{5(pp128-130)} The AMEDD process basically has 5 steps: abeyance or summary suspension, investigation, professional peer review, hearing, and appeal. Action taken by the commander or his/her delegate to hold in abeyance, to deny, or to summarily suspend clinical privileges is proper when there is reasonable cause to doubt the individual's competence to practice or for any other cause affecting the safety of patients or others. Reasonable cause includes but is not limited to: a single incident of gross negligence; a pattern of inappropriate prescribing; a pattern of substandard care, negligence, or incompetence causing death or serious bodily injury; abuse of substance or diagnosis of alcohol dependence; documented impairment and refusal or failure by the individual to complete rehabilitation; a psychiatric disorder that is not responsive to treatment; and significant unprofessional conduct. Note that if an acute or chronic medical problem, mental health condition, or alcohol/drug impairment interferes with the provider's performance of clinical duties, the provider will submit a request to appropriately modify his/her privileges or scope of practice. This modification is not considered an adverse privileging action, but is governed in accordance with chapter 11 of *Army Regulation 40-68*.^{5(pp94-101)} Although the responsibility for invoking and processing adverse actions lies primarily with the MTF commander, section 10-3 of *Army Regulation 40-68*^{5(p72)} requires consultation and coordination as follows:

- With the servicing staff judge advocate prior to proceeding with any adverse privileging action, to help ensure that legal guidance is followed throughout the process.
- With the regional medical command/regional dental command (RMC/RDC) for guidance on procedures and to discuss plan of action, since RMC/RDC is responsible for process oversight, and for appeals from MTFs. For appeals from medical centers or involving RMC/RDC personnel, the US Army Medical Command or Dental Command will provide oversight and serve as appellate authority.
- With civilian personnel employee relations specialist prior to any adverse privileging action relative to a civil service employee, to ensure compliance with established civilian employee guidance.

Adverse Privileging Actions in the Army Medical Department



Schematic representation of the Army Medical Department adverse privileging action process.

- With the appropriate contract officer if an adverse privileging action is being considered on a contract employee, to ensure compliance with the contract in place.
- With US Army Medical Command (MEDCOM) Office of the Staff Judge Advocate (OSJA). Section 10-3c of *Army Regulation 40-68*,^{5(p72)} requires that the MEDCOM OSJA review all adverse privileging/practice actions prior to final action by The Surgeon General.

ABEYANCE/SUMMARY SUSPENSION

The commander must act when a provider's conduct, condition, or performance requires action to protect the health or safety of patients. In situations where the threat to patient safety or the incompetence is not clearly defined, the commander, deputy commander for clinical services, or the provider's department chief may place the provider's privileges in abeyance. An abeyance is not an adverse action, but formally places

the provider on notice that scrutiny of his/her practice has begun which may result in an adverse privileging action or administrative action. The initial abeyance period is 15 days, and may be extended for an additional 15 days by the commander with written notice to the provider, if necessary for investigation and committee consideration. On the 31st day following initiation of an abeyance, the action becomes a summary suspension. Where the individual's misconduct, professional incompetence, or negligence is obvious and poses a clear and evident threat to the safety of patients or well-being of others, a summary suspension of clinical privileges should be the initial course of action. Summary suspension of privileges is not an adverse privileging action, but signals the need for an investigation into the practice or conduct of the provider. Whether the initial action is abeyance or summary suspension, the provider is entitled to written notification specifying the basis for the initial action, naming the action, the duration of the action, and that a quality assurance (QA) investigation will be conducted and results reviewed by the credentials committee. Forms of written notice and the written provider acknowledgement are provided in Figures 10-1 and 10-2, respectively, of *Army Regulation 40-68*.^{5(pp85-86)} In the case of an abeyance, the MTF commander has discretion to withdraw permission for off-duty employment (ODE); however, withdrawal of permission for ODE and notification of the facility/clinic where the provider is engaged in ODE are mandatory for summary suspension cases. Further, there can be no approval of ODE applications until privileges are restored at the MTF.

INVESTIGATION

Section 10-6d of *Army Regulation 40-68*^{5(p75)} requires an immediate and rigorous investigation to collect relevant facts and information in every case of abeyance or summary suspension. The MTF commander will appoint a disinterested third party to conduct the investigation and to report the results to the credentials committee or the appropriate department chief if the provider is not privileged. The investigating officer (IO) should be reminded that all information, testimony, findings, recommendations, and documentation connected with a QA investigation are quality assurance information, and any release is subject to 10 USC §1102 and Appendix B of *Army Regulation 40-68*^{5(pp128-130)}. The QA investigation may

include voluntary consultation with the provider in question, review of relevant documents, or discussions with individuals having knowledge of the situation. When the investigation is complete, the report submitted by the IO will present the factual findings with appropriate justification or details and may include the IO's conclusions and recommendations. The MTF credentials committee (or credentials function) will review the IO's report and other pertinent information and recommend one of the following to the commander:

- No further action be taken (if available evidence did not warrant a privileging action) and the provider's privileges be reinstated
- Monitoring and evaluation
- A formal peer review

Monitoring and evaluation (M&E) is defined in the draft DoD manual as a well documented plan of intensified peer review to confirm a provider possesses the skill, knowledge, and ability to render safe and effective healthcare. The M&E documentation plan must include clear expectations and measures of success that will be routinely reviewed throughout the period of M&E.

FORMAL PEER REVIEW

If the credentials committee's recommendation for formal peer review is approved by the commander, the requirements in chapter 10-6f of *Army Regulation 40-68*^{5(p76)} apply. Formal peer review is required whenever a standard of care determination must be made or if a provider's performance is such that an adverse privileging/adverse practice action may be indicated. The intent of a formal peer review is to evaluate the provider's performance, conduct or condition to determine the extent of the problem(s) and to make recommendations through the credentials committee to the commander. The provider must receive written notice of the date, time and location of the peer review; a statement of the alleged facts, events, conduct or omissions subject to review, the provider's right to submit a written statement, and the rights of appearance as set out in section 10-6f(2) of *Army Regulation 40-68*.^{5(p76)} The conclusions reached by the peer review panel should be supported by rationale that specifically addresses the issues for which the peer review was conducted.

Adverse Privileging Actions in the Army Medical Department

The peer review panel must be composed of at least 3 clinical peers of the involved provider, meaning they possess similar clinical specialty, education and training. If the MTF does not have 3 peers available to conduct this review, it may be accomplished using peers from other MTFs, and the meeting may occur in person or via video or teleconference. The following are not appropriate participants as voting members of a peer review panel:

- Neither the provider's direct supervisor, nor the provider's subordinates
- The individual who suspended the provider's privileges
- Any person who investigated the case (including the IO)
- Any person whose testimony is expected to be significant in the case
- Any person who is participating or has participated in any other administrative proceeding or court-martial board involving the provider
- Any person who is reviewing or has reviewed the provider's actions under consideration
- The credentials/risk management committee chairperson

The peer review panel may make one of the following recommendations: reinstatement, monitoring and evaluation (M&E), suspension, restriction, reduction, revocation, or denial. The array of recommendations are further defined in Chapter 10-6f(5) of *Army Regulation 40-68*.^{5(p75)} Within 7 calendar days of completing the peer review, the panel's recommendations, along with the evidence considered, will be forwarded to the credentials committee. The credentials committee will include its recommendation(s), which may or may not coincide with those of the peer review panel, and the entire case file with recommendations will be forwarded to the commander.

The commander has 14 calendar days from receipt of the recommendations to review and decide what privileging action to take based on the facts provided. Although not bound by the recommendations of the credentials committee or the peer review panel, the commander's decision must be supported by the facts of the case. The commander must provide written notice to the provider of the privileging action to be

taken and the justification, addressing all specified allegations. A form of notification is at Figure 10-4 of *Army Regulation 40-68*.^{5(p89)} If the provider is a contract provider, a copy of the notification is forwarded to the responsible contracting office, and a letter documenting the actions is provided to the contractor at the address of record. If the proposed action is other than reinstatement or M&E, the provider must also be advised in writing of his/her hearing and appeal rights. The provider must have access to all information considered by the credentials committee and the MTF which resulted in the basis of the preliminary action.

REQUEST FOR HEARING AND WAIVER

Section 10-7b of *Army Regulation 40-68*^{5(p78)} currently requires the provider to request a hearing in writing to the credentials committee chairperson within 10 duty days from the date of receipt of the notification of recommended adverse privileging action. This time frame will likely be changed to not less than 10 nor greater than 30 calendar days when the DoD manual is published. The provider may voluntarily waive his/her right to a hearing by not requesting a hearing within the specified time frame, or by failure to appear at a scheduled hearing, absent good cause as determined by the commander. Note that if the provider is unable to appear in person at the hearing, alternate means of obtaining his/her personal participation will be offered to include written deposition or telephone conference call. Waiver of hearing rights includes waiver of appeal rights. When a hearing is waived, the recommendations from the credentials committee and peer review panel are forwarded to the commander for review and decision. The written decision and the provider's notice of the commander's decision will be filed in the provider credentials file, with appropriate forwarding through the regional medical command to MEDCOM Quality Management Division for reporting to The Surgeon General, and possibly the NPDB.

HEARING BOARD NOTIFICATION AND COMPOSITION

The Deputy Commander for Clinical Services or other physician designated by the commander will chair the hearing board. The chairperson will advise the provider in writing, delivered in person, with provider receipt acknowledged by signed memorandum of the following:

- a) The adverse privileging action under consideration that is the grounds for the hearing, any specific dates, facts and all pertinent documents applicable to the case.
- b) The time and location of the hearing.
- c) The names of the witnesses who will be called to testify at the hearing.
- d) The provider's right to be present, to submit evidence, to question witnesses and to provide witnesses on his/her behalf.
- e) The right to have legal counsel present.

The notice requirement is discussed more fully in section 10-8 of *Army Regulation 40-68*,^{5(pp78-80)} and a form for provider notification of hearing is provided at Figure 10-6.^{5(pp91-92)}

The hearing board composition may be a subset of the credentials committee, or the entire credentials committee may perform this function, according to local MTF policy, subject to the following requirements. The IO and any member of the peer review panel may not be a voting member of the hearing board, and at least one voting member of the hearing board must be a privileged provider from the same discipline as the provider requesting the hearing.

HEARING BOARD PROCEDURES

The hearing will be fair and impartial, and is intended to provide a thorough review of the material presented, including that submitted by the provider. The fair hearing is an administrative proceeding; therefore, the rules of evidence prescribed for trials by courts-martial or in courts of law are not applicable. The chairperson will serve as presiding officer of the hearing board and as such, will open the hearing, ensure the orderly presentation of evidence and timely progression of the proceeding, dismiss any unruly person, rule on any objections, and will only vote in the event of a tie. If criminal misconduct by the provider, including dereliction of duty, is known or suspected, the chairperson will advise the provider of his/her rights, using Department of the Army Form 3881 (Rights Warning Procedure/Waiver Certificate). The hearing is closed to the public, however, the provider may request that the chairperson permit observers. The chairperson will normally grant the request but may limit the number of observers and may exclude anyone

who is disruptive to the proceedings, at the chair's discretion. The chairperson should issue a reminder to all involved at the opening of the hearing that the hearing is considered a QA activity covered by 10 USC §1102 and information from the proceedings is not for release by any individual. Additionally, no recording devices, other than that used by the designated recorder to prepare the record, are permitted in the hearing. Witnesses will be called in to the hearing room to provide their testimony and answer questions from the hearing board and the provider, and will then be excused from the hearing room. After the presentation of all evidence and relevant information, the provider and his or her representatives will be excused, and the hearing board will deliberate in closed session to determine its findings and recommendations.

In addition to tape recording, the hearing will be documented in summarized minutes that reflect all the salient details of the proceedings. The documentation must show that each of the hearing board's findings is supported by a preponderance of the evidence, in other words, each finding must be supported by a greater weight of evidence than supports a contrary conclusion. Specific incidents or situations will support general statements by the hearing board. To substantiate the findings of the hearing board, copies of pertinent medical and/or dental records or case histories will be included in the record of the proceedings.

Recommendations by the hearing board may include, but are not limited to:

- Reinstatement of privileges
- Identification of specific provider deficiencies that require improvement and the establishment of requirements such as consultation with other providers or specialists related to patient care management
- Suspension, reduction, or restriction of clinical privileges for a specified length of time, including a recommendation that the provider be released from active duty or federal employment
- Revocation of clinical privileges
- Reconvene the hearing, after appropriate notice to the provider, to consider additional relevant evidence.

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The decision of the hearing board is determined by vote of the majority. Following deliberation, each hearing board member will cast a vote by secret ballot, either for the findings and recommendations or against them. Abstention is not permitted.

The record of the hearing, including the findings and recommendations, will be reviewed by the executive committee of the medical staff (ECMS) prior to forwarding to the MTF commander. All qualified members of the ECMS (excluding hearing board members, the investigating officer, and peer review panel members) will either concur by endorsement with the recommendations of the hearing board or submit separate recommendations. If an ECMS member is absent and unable to review the hearing board report, the absence will be noted and the case forwarded to the commander without endorsement by the absent member. The servicing staff judge advocate will review the record, including credentials committee/peer review panel findings and recommendations and any input from the provider for legal sufficiency prior to action by the commander.

The commander will review the hearing record and make a decision regarding the provider's privileges. The hearing board's findings and recommendations are advisory only, and not binding on the commander. Written notice of the commander's decision, with the date of delivery annotated on it, will be furnished to the provider either in person or by certified return receipt requested mail. The signed receipt acknowledges the provider's receipt of the commander's decision. If the commander decides to deny, suspend, restrict, reduce, or revoke the provider's privileges, the written notice should advise the provider of his or her right of appeal, and that the provider will be given a copy of the hearing record upon request. The written notice of the commander's decision should specify that the provider has 10 duty days to submit a request to the commander for reconsideration. The commander may extend the 10 duty day time limit in writing at the request of the provider for good cause. A copy of the notice will be placed in the provider's provider credentials file and the appropriate department, service, or clinic chief will be advised of the decision.

RECONSIDERATION AND APPEAL

The burden is on the provider to specify the grounds for reconsideration and appeal. If the provider does not

request reconsideration, the adverse privileging action and all information pertaining to the case will be submitted to the MEDCOM Quality Management Division, with copy furnished to the regional medical command for reporting to the NPDB. If the provider elects to appeal the commander's decision, he/she will submit a formal request that identifies the errors of fact or procedure that form the basis of the request. The commander has 14 calendar days to consider the request for reconsideration. If the commander denies the request in whole or in part, the action is automatically endorsed to The Surgeon General as an appeal. The Surgeon General is the final appellate authority for denying, suspending, restricting, reducing, or revoking clinical privileges. The written appeal and all information pertaining to the case will be submitted through the commander of the appropriate regional medical command or regional dental command (RMC or RDC) using certified mail (return receipt-requested). The RMC or RDC commander will review the packet to ensure all necessary information is included prior to forwarding the case to the appropriate staff office that will conduct the appeal. If the appeal involves medical center, RMC, or RDC providers or commanders, the MEDCOM Quality Management Division will convene the appeals board. Otherwise, the RMC or RDC is responsible for convening appeals boards from the subordinate MTFs.

APPEALS PROCESS

The appeals board will consist of a minimum of 3 privileged providers, one of whom will serve as chairperson and all of whom will be voting members. At least one member of the appeals board should be of the same discipline and specialty as the provider whose appeal is under consideration. If the provider is a dentist with no medical facility privileges, the appeals board will consist of 3 dental officers. If the dentist has medical facility privileges which are under review, the committee will include one privileged physician and 2 dental officers, one with medical facility privileges, if possible. If the action is against a dental officer with hospital privileges, but the action involves only the dental privileges, the appeals board will consist of 3 dental officers.

The standard for the appellate review is whether there is substantial evidence to support the MTF commander's decision. After evaluating the merit of the appeal in light of the provider's basis for appeal

and considering all information in the record, the appeals board will advise the convening commander (MEDCOM, US Army Dental Command, RMC, or RDC, as appropriate) of its findings and recommendations for disposition, and whether it finds substantial evidence to support the MTF commander's adverse privileging action. Findings and recommendations of RMC-level appeals will be endorsed by the RMC commander and all documents considered by the appeals board will be forwarded by certified return receipt requested mail to the MEDCOM for review and approval by The Surgeon General, the sole authority responsible for provider notification of the final decision associated with an appeal. No other party has input into that final decision. The appellate authority will notify the provider of the decision on the appeal by certified return receipt requested mail as soon as possible following adjournment of the appeals board. The RMC or MTF commander, as appropriate, will also be notified in writing, with clear guidance as to what actions the MTF is expected to take regarding the future utilization of the provider.

Of note is that any subsequent administrative action to separate a provider as a result of an adverse privileging action must be deferred pending appeal resolution. Providers who voluntarily separate prior to resolution of their appeal must be informed in writing that the process will be completed as though they were still on active duty or employed in a civilian capacity. Only The Surgeon General is authorized to report AMEDD

healthcare personnel to the appropriate professional regulating authorities, including the NPDB, the Federation of State Medical Boards, state licensing boards, and other regulatory agencies.

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AUTHOR

Ms Gagliano is Health Care Law Attorney-Advisor in the Office of the Staff Judge Advocate, Headquarters, US Army Medical Command, Fort Sam Houston, Texas.



US Army Medical Command Intellectual Property

Elizabeth Arwine, JD
Jill Caldwell

Intellectual property is a hot topic today. The world's most successful companies recognize the enormous financial and competitive power that resides in an intellectual property portfolio. In our knowledge and technology based economy, the intangible products of the mind—inventions, original works of authorship, and know-how—have taken on paramount importance. The *New York Times* recognized that “intellectual property has been transformed from a sleepy area of law and business to one of the driving engines of a high technology economy.”¹ US Army Medical Command (MEDCOM) inventions play an important role in achieving the Army's mission and the stimulation of the US economy. Inventions arising from the MEDCOM laboratories, hospitals, and clinics are often dual-use technologies—inventions useful for both the Warfighter and civilian sectors. This article is an introduction to some of the many federal laws and agency-specific regulations that govern the creation, protection, ownership, and transfer of intellectual property arising from federal research.

BASIC INTELLECTUAL PROPERTY ASSETS

Patents, trademarks, copyrights, and trade secrets are considered to be the 4 main types of intellectual property (IP), defined as the intangible product of the human mind. Some say that it is imagination made real. IP is personal property, and like other personal property, it can be owned, used, given away, sold, or even “rented” under a license. It is an asset like equipment or investments, and should be protected from theft, misuse, and misappropriation.

PATENT

A patent is a grant to the inventor by the federal government of a limited time right to exclude others from making, using, offering to sell, selling or importing the invention that is claimed in the patent document. A patent may be obtained for inventions comprising a process, machine, an article of manufacture, composition of matter, or any new and useful improvement thereof. Examples may include

chemical compounds and processes, a process for purifying or expressing a protein, some types of software, medical diagnostic devices, medical imaging, vaccines, etc. Almost anything is patentable so long as the invention is new, useful, and unobvious when compared to what has come before. Improvements of existing inventions are also potentially patentable, such as a new use of a known process or compound.

TRADEMARK

A trademark is a name, symbol, logo, combination or other device, including color and sound, that indicates the source and quality of goods and services and distinguishes those goods and services from those of competitors. “Made up” or arbitrary marks are stronger and confer more protection than descriptive marks. An example of a strong arbitrary mark is Apple Computers. The shape of a Coca Cola bottle is also a familiar trademark. Sounds like the MGM lion's roar and the NBC chimes can also be trademarks, as can slogans like “you've got mail.” Colors like the pink of the Owens-Corning insulation can be used as a trademark identifying the source of that particular product.

COPYRIGHT

Copyright protects original works of authorship such as writings, music, and works of art that have been tangibly expressed and fixed in some medium. Copyright protects the expression of an idea as that expression is embodied in the work, but not the idea itself. A copyright is an exclusive right to reproduce the copyrighted work, distribute copies of the work to others, perform or display the work in public, and prepare derivative works based upon the original work. In order to obtain a copyright, the work must be independently created and possess some degree of creativity. Purely factual works are not copyrightable. Reformatted works could be copyrightable if the level of creativity in the reformatting meets the copyright office standard.

Works made by federal government employees as a consequence of their official duties are not copyrightable. The federal government can, however, hold and license copyrights that are assigned to it by those capable of obtaining copyright protection, such as contractors. If a work was authored jointly by a government employee and a nongovernment employee, those portions of the work authored by the government employee are not copyrightable.

TRADE SECRET

A trade secret is information that an organization may choose to keep secret to give that organization an advantage over its competitors. It is generally technical or business information that possesses economic value from not being known to other persons who can derive economic value from its disclosure or use.

Although the government does not possess its own trade secrets per se, government employees are responsible for protecting the financial or proprietary business information of current and potential vendors or collaborators. There are 2 federal acts pertaining to trade secrets, one that makes it a crime to steal trade secrets and one that makes it a crime for a federal government employee to release confidential or proprietary information gained during the course of his or her employment.^{2,3}

PATENT LAW

An invention must be useful, novel, and nonobvious to be patentable. For example, if the inventor makes a new chemical but cannot identify a use for the chemical, he cannot obtain a patent. The invention must also be something new. It cannot have been already described in a printed publication, used, known, or patented. Finally, a patent cannot be obtained on an invention that, although novel, comprises elements that, when considered as a whole, results in an invention that would have been obvious to others working in that field at the time it was made. Note that this is a very general description of a complex legal concept.

There are also events that, if they occur, prevent an inventor from obtaining a patent on his or her invention.⁴ If an inventor publicly discloses his invention prior to applying for a patent (for example, publicly using it, presenting detailed information at a scientific conference or open meeting, publishing a journal article about it, demonstrating it, displaying it,

or selling it), he may not be able to obtain a patent on that invention in the United States unless a patent application is filed within one year of the invention's public disclosure.⁵ Inventors should consult a patent attorney if a public disclosure has been made. Determining whether patent rights have been lost is complicated and not all public disclosures are damaging.

There are 3 types of patents: plant, design, and utility. Plant patents protect invented or discovered, asexually reproduced new and distinct plant varieties. A design patent consists of the visual ornamental characteristics embodied in, or applied to, an article of manufacture. Design patents can be obtained for new, original, and ornamental designs for articles of manufacture. For example, the shape of a bicycle helmet, the look of an athletic shoe, and the pattern and shape of a lampshade can be protected by design patents. Utility patents protect the functional aspects of the invention. In general terms, a "utility patent" protects the way an article is used and works while a "design patent" protects the way an article looks. Applications for utility patents are the most common type of patent application filed for MEDCOM inventions.

There are 2 types of utility patent applications: the nonprovisional and provisional applications. (Note: provisional patent applications may also be filed for plant patents.) A nonprovisional application, also known as a regular or nonprovisional utility patent application, begins the examination process and ultimately may lead to an issued patent. A provisional patent application establishes a filing date which is strategically important but does not begin the examination process. A provisional patent application will never result in a patent. It is generally used in emergency situations such as imminent public disclosure. A provisional application also provides the inventor with a one-year period to further develop the invention, determine marketability, acquire funding or capital, or seek licensing agreements. The regular patent application must be filed within one year of the provisional filing date in order to claim the benefit of that earlier filing date.

PATENT APPLICATION SUBMISSION, EXAMINATION AND TERM

Patents are obtained through a complex and usually lengthy administrative proceeding requiring a unique blend of scientific and legal skills to navigate. Scientist-patent attorney/agent partnerships are essential to

successful patent prosecution. A patent application is the most complex and sophisticated of legal documents. The patent application is prepared by the patent attorney or patent agent with the assistance of the inventor, based upon the invention disclosure and all relevant information, publications, and patents available. Upon submission to the US Patent and Trademark Office (USPTO), the patent application is assigned to a patent examiner, who is deemed by the USPTO to be an expert in the technology covered by the patent application. The patent examiner will determine whether the application complies with legal requirements and if the invention is new, useful, and nonobvious.

Under current law, the patent application will usually be published online by the USPTO about 18 months after the filing date. The application, examination correspondence, and issued patents are published on the USPTO website (www.uspto.gov). Searches of published patent applications and issued patents by various fields and keywords can also be conducted on that website.

Utility patents have a term of 20 years, calculated from the filing date of the patent application. If, for example, 3 years pass in the examination process between filing of the application and issuance of the patent, the effective term of patent protection is 17 years. The amount of time it takes for examination of an application depends upon many factors, including the nature of invention, the complexity of the invention, and the body of prior knowledge relevant to the invention. Today, on average, it takes from 2 to 5 years for the examination and issuance of a patent. Mechanical inventions, for example, tend to move through the examination process more rapidly than chemical or biological related inventions. This may be, in part, because mechanical devices operate under known and predictable physical and mechanical principles. Chemical and biological inventions also operate under known physical laws (for the most part), but their mode of operation may not be as predictable as mechanical inventions. These applications usually take about 3 to 4 years to issue into patents. Software inventions tend to move through the process even more slowly as applications for software related inventions are very complex. It is not unusual for software applications to remain pending in the USPTO for 5 years or more.

PATENTING EXPENSES

Obtaining a patent can be very costly. The costs of obtaining a patent depend upon, among other things, the complexity and length of the patent application, the difficulty encountered in obtaining an allowance during the examination process, the cost of patent attorney or agent services, patent office fees, and whether the patent application or patent is challenged. The services of patent attorneys and patent agents are expensive. Both patent attorneys and agents have scientific degrees but patent agents are not attorneys. Both are registered to practice before the USPTO, but patent agents may not represent an inventor in court, nor may a patent agent draft legal documents, such as assignments, for inventors. As a patent attorney has both a scientific degree and a law degree, the fees generally reflect these additional qualifications and expertise.

OWNERSHIP AND ASSIGNMENT OF INVENTION

Patent applications are filed in the name of the federal government employee inventors, but the government, subject to exceptions, owns all the rights to any invention

- made by any government employee during normal working hours, or
- which bears a direct relation to or is made in consequence of the official duties of the inventor, or
- to which the government contributed facilities, equipment, materials, funds, information, or time or service of other government employees on official duty.

Government employee inventors who believe that the ownership of the invention should reside with them can request an invention rights determination. Even if the invention was made before the inventor became a government employee or it is clearly unrelated to his or her duties, it is wise to request and receive an invention rights determination in order to remove any potential cloud upon the title of the invention.

Private sector employees are usually required by their employment contracts to assign all rights in any inventions they make to their employer. As different organizations have different policies, nongovernment employee inventors should always consult their employment contract to determine whether they are

obligated to assign rights in the invention to their employer.

PATENTS IN FOREIGN COUNTRIES

The patent grant provides protection and confers rights to a patentee only within the United States and its territories. If foreign protection and rights are desired, a patent must be obtained in the foreign country. There are alternative routes to obtaining patent protection in foreign countries. Note that foreign patents cannot be obtained if there has been any public disclosure of the invention before the application filing date. Only in the United States does an inventor have a one-year grace period between public disclosure and the filing of his or her patent application. Once the invention has been publicly disclosed, foreign rights are lost unless a patent application has already been filed for that invention.

INTELLECTUAL PROPERTY RESULTING FROM FEDERALLY FUNDED RESEARCH

The Bayh-Dole Act⁶ provides the statutory basis for federal technology transfer activities, including the patenting and licensing of inventions made under federal funding agreements by recipients of those funds. The Act applies to inventions made as a result of a federal funding agreement such as a grant, cooperative agreement, or contract. The Act permits recipients of federal funding to elect to take title to any invention that arises from performance of the federal funding agreement. If the recipient of the federal funding agreement elects to take title, the recipient must file patent applications, seek commercialization opportunities, and report to the funding agency on its efforts to obtain use of the invention. In return, the government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to make or practice the invention or have the invention made or practiced on behalf of the United States. The government may make or use the invention that was made under the federal funding agreement. In addition, the government may have the invention made or used for it by other parties as long as these actions are for the government's benefit. The government, however, may not grant licenses for commercial exploitation of the invention.

The right of the recipient of federal funding to take title is conditioned upon fulfilling its obligations under the Bayh-Dole Act in a timely fashion. The recipient

must report the making of and disclose the invention to the government within a reasonable time after the recipient's inventor discloses the conception or making of the invention to recipient's representative responsible for the administration of patent matters.⁷ The Bayh-Dole Act does not define "reasonable time," but corresponding Federal Acquisition Regulation (FAR) provisions require reporting of the invention to the government within 2 months after the inventor reports it to his or her employer.⁸ Electing title and filing patent applications are also subject to time constraints identified in the FAR.⁹ If the recipient of federal funding elects to take title to the invention, the federal agencies generally require the recipient to execute a document confirming this license to the government which is filed at the USPTO. If a recipient of federal funding declines to take title or fails to meet their Bayh-Dole obligations within the time limits provided, the government may take title to the invention, and has on occasion done just that.^{10,11}

INTELLECTUAL PROPERTY ARISING FROM COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS

A Cooperative Research and Development Agreement (CRADA) is a written agreement establishing a collaborative research relationship between a federal laboratory and a partner. The CRADA partner can be a person or an entity from industry, state government, local government, academic institutions, nonprofit organizations, or another federal laboratory.¹² A CRADA allows the federal government and nonfederal partners to optimize their resources, share technical expertise, develop and share intellectual property arising from the collaborative effort, and speed the commercialization of federally developed technology. A CRADA may provide protection for any proprietary information brought into the CRADA relationship by the partner. The terms of a CRADA may also allow parties to the CRADA to keep research results confidential and free from disclosure through the Freedom of Information Act¹³ for a certain period of time. A CRADA permits the government and the partner to share in intellectual property rights. A federal laboratory may provide IP, with or without direct reimbursement. The federal laboratory may contribute federally owned patents, trademarks, copyrights, information, or know-how to the collaborative effort. A nonfederal CRADA partner may also provide the same types of IP.

US Army Medical Command Intellectual Property

All types of intellectual property can arise from the collaborative effort. However, data and inventions tend to be the most common products resulting from a CRADA. The rights and obligations of the parties with respect to data and intellectual property are usually set out in the terms of the original CRADA, or a subsequent amendment or modification to the CRADA. The terms of the CRADA control the disposition of the intellectual property. However, other laws such as the patent or copyright statutes and case law may affect the disposition of those intellectual property rights. For these reasons, the terms of the CRADA must be interpreted in light of other applicable statutes, regulations, or case law.

LICENSING OF FEDERALLY OWNED INVENTIONS

The federal government's policy promotes the full utilization of government-owned inventions by licensing inventions to the private sector. Licensing of federally owned inventions and other intellectual property is effected through a license. A patent license agreement (PLA) is a contractual agreement granting the right to use or practice a government-owned invention in exchange for something of value, usually royalties and other payments. Inventions described in issued patents and/or patent applications, both domestic and foreign, may be licensed under a PLA by the federal facility.

Main Types of Licenses

Each federal agency is authorized to grant nonexclusive, exclusive, or partially exclusive licenses to federally owned inventions, royalty-free or for royalties or other consideration on such terms and conditions as determined appropriate in the public interest.¹⁴ A license does not transfer ownership of the invention or other intellectual property being licensed—the federal agency remains the owner of the intellectual property. A license is only a promise by the licensor not to sue the licensee for actions performed by the licensee that are within the scope of the license agreement.¹⁵

A nonexclusive license permits the licensee to practice the invention or other intellectual property described in the licensed patent or patent application. The licensor (the government in this case) will still retain the ability to practice the invention. In addition, the licensor may also license the invention or other intellectual property to another licensee, thus the term “nonexclusive.” A true exclusive license allows only the exclusive licensee to practice the invention or other intellectual

property. The patentee may not practice the invention, nor may he license another to do so. Many “exclusive” licenses reserve to the owner of the intellectual property a right to practice the invention. Because there are no other third-party licenses, this type of license is referred to as an “exclusive” license. A partially exclusive license may be directed to specific geographic areas of use, to specific fields of use (home or hospital), to various markets for a product (retail or wholesale), or for limited periods of time less than the full term of the patent. A licensee might receive exclusive license rights in his particular industry, whereas another licensee might receive exclusive license rights in her different, unrelated industry. A partially exclusive license allows the licensor to create license revenue without generating competition between the licensees or in the patentee's own market.

Terms and Conditions for All Licensees

The terms of the PLA are usually negotiated by representatives from the federal laboratory's Office of Research and Technology Applications. The terms and conditions (financial and otherwise) included in the PLA will depend on many factors. The licensor and licensee should consider the stage of development of the technology being licensed, whether the license is for a single invention or a patent portfolio, whether the invention requires regulatory approval (for example, new drugs are regulated by the US Food and Drug Administration), the potential end user market (for example, the need for the product, commercial potential, and the size of the market), and the licensee's ability to finance, manufacture, and market the invention. Although there is a certain amount of flexibility regarding the terms and conditions that will be placed into a PLA, there are certain terms and conditions that are required by statute or regulation. (Note: The Secretary of Commerce is authorized to promulgate regulations specifying the terms and conditions upon which any federally owned invention, other than inventions owned by the Tennessee Valley Authority, may be licensed on a nonexclusive, partially exclusive, or exclusive basis.¹⁶) With respect to all licenses, the government must retain a royalty-free, irrevocable license to practice and have practiced the invention on behalf of the United States.

INCENTIVES FOR GOVERNMENT LABORATORIES AND INVENTORS

In addition to stimulating future research and development collaborations with the private sector, a

PLA has the potential to result in products that the government needs. For example, licensing of Department of Defense inventions may result in better products for the Soldiers, Marines, Sailors, and Airmen. A PLA may also generate much needed income for the federal laboratory. A federal laboratory may take 80% of any royalties it receives from a PLA and use those funds as the director deems appropriate. Many laboratories reinvest those funds in research and development, purchase needed supplies, services, or training. A PLA may also facilitate the government's access to improvements of the licensed invention or other intellectual property. By licensing technology, the potential exists for development of alternative or supplemental sources of goods and services to the government. Finally, PLAs enhance the prestige of the federal laboratory and its scientists.

A portion of the royalty income received through the PLA goes to the government employee inventors of the licensed invention. The government coinventors can receive up to 20% of any royalties received by the federal laboratory. There is a limit of \$150,000 in royalties that any single government inventor can receive in any given year. The cumulative cap of \$150,000 covers all inventions of a particular inventor that may be licensed. Of the royalties received by the federal laboratory, the first \$2000 goes immediately to the government inventors. Note that government employee inventors cannot participate in PLA negotiations concerning the financial aspects of the license as that is a conflict of interest. The government employee inventor can, however, provide input concerning commercial potential and technical aspects of the invention.

CONCLUSION

The MEDCOM has a significant domestic and foreign patenting program that has resulted in many licensed inventions that are used in hospitals, clinics, and laboratories or by private sector companies. Many other inventions are in advanced development for regulatory approval and transition into the private sector. This article only touches upon some of the many facets of intellectual property practice and generalizes highly complex concepts.

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AUTHORS

Ms Arwine is Chief Patent Attorney and Intellectual Property Counsel at the Office of the Staff Judge Advocate, US Army Medical Research & Materiel Command (USAMRMC), Fort Detrick, Maryland.

Ms Caldwell is Patent Paralegal at the Office of the Staff Judge Advocate, USAMRMC.

Gifts of Travel Benefits from Nonfederal Sources to Military and Civilian Government Employees

MAJ Joseph B. Topinka, JAG, USA

INTRODUCTION

Medical personnel in the US military are extensively educated, trained, and experienced professionals whose expertise is in high demand. These individuals are often invited to attend scientific or medical conferences, to present papers, to give presentations, or to provide technical instruction to, or collaborate with, nonfederal entities (NFEs). Such private entities are often professional associations, medical supply companies, potential technical transfer partners, universities, and other hospitals. These entities are frequently willing to provide airfare, lodging, and meals for the invitee in exchange for the invitee's expertise.

Acceptance of travel benefits by government employees is governed by several statutes and regulations. The overall purpose of these statutes and regulations is to ensure that government employees are not placed in a position where they could potentially be influenced in the performance or nonperformance of their official duties.

ACCEPTANCE OF OFFICIAL TRAVEL BENEFITS IN-KIND OR PAYMENT FOR OFFICIAL TRAVEL EXPENSES

In general, official travel by government employees is funded by the federal government except that government employees in the US military may accept travel benefits (including in-kind subsistence, accommodations, and payments or reimbursements of expenses) from NFEs as provided in 31 USC §1353, 41 CFR Part 304, and chapter 4 of the *Department of Defense (DoD) Joint Ethics Regulation (JER)*.^{1(pp45-54)} Chapter 4 of the JER does not apply to travel benefits provided to US military employees in their personal capacities, however, employees must report such travel expenses

in personal financial disclosure reports as required in accordance with chapter 7 of the JER.^{1(pp79-91)} There may also be limitations on the acceptance of travel benefits in one's personal capacity, including restrictions on acceptance of gifts from prohibited sources, those given because of the employee's federal position, as well as under 41 USC §423.

Government employees in the US military may also accept travel and travel-related expenses from a foreign government. Criteria used to determine whether it is appropriate to accept travel expenses of more than "minimal value" may be found at 5 USC §7342, *DoD Directive 1005.13*,² and JER, paragraph 2-300b.^{1(p26)} This amount is adjusted every 3 years and is currently set at \$335 (as of January 1, 2008). Payment of such expenses may be accepted if travel begins and ends outside the United States, except when travel across the United States is the shortest, least expensive, or only available route. Such travel must be in the best interests of the US military and the US government, considering all the circumstances.

Acceptance procedures are straightforward. All official travel benefits accepted from NFEs must be approved in writing by the travel-approving authority, upon the advice of an ethics counselor and approved in advance of travel, if accepted under the authority granted by 31 USC §1353, in accordance with 41 CFR 304-3.12 and JER, paragraph 4-100c(2).^{1(p45)} However, acceptance may be authorized after the travel has begun if a number of criteria are met in accordance with 41 CFR 304-3.13. The latter procedure is often very difficult and should be avoided if possible by acquiring approval in advance of the travel.

This article is based on material developed by COL Samuel Smith, former Center Judge Advocate, Walter Reed Army Medical Center, and LTC (Ret) Margaret Schulyer, former Judge Advocate, US Army Medical Research and Materiel Command, Fort Detrick, Maryland. The subject material was included in a deskbook used in military legal conferences and presentations, and for online reference purposes.

The Author

In accordance with 31 USC §1353, the JER, Federal Travel Regulations (41 CFR 300-304), and 41 CFR 301-1.2 and 304, travel expenses can be accepted by US military employees in connection with their attendance in an official capacity at “a meeting or similar function.”

Government employees may not generally accept travel benefits from a prohibited source as it could cause a reasonable person to question the integrity of government operations. A prohibited source is an entity whose interests may be substantially affected by the performance or nonperformance of a given employee’s duties.³ Army ethics counselors serve a vital role in conducting an analysis to determine whether an NFE can be classified as a prohibited source. Factors considered in this analysis include:

- The identity of the NFE.
- The purpose of the meeting or event.
- The nature and sensitivity of any matter pending at the agency which may affect the interest of the NFE (which includes a check of the current Department of the Army contractor list).
- The significance of the employee’s role in any such matter.
- The monetary value and character of the travel benefits offered by the NFE.

Acceptance of official travel benefits from nonfederal sources for attendance at meetings or similar functions requires the concurrence of an ethics counselor. A sample of a memorandum to document the nonfederal entity offer to provide travel benefits to Department of the Army personnel, and concurrence or nonconcurrency by the ethics counselor is provided on page 66. The standard for analysis is whether a reasonable person with knowledge of all relevant facts could conclude that the travel is for an official purpose and is for attendance at a qualifying meeting or other similar function. The employee’s attendance at the meeting or function must be appropriate and consistent with the interests of the organization.

US military employees (including their spouses) cannot accept cash travel payments or checks made out to the employees on behalf of the federal government. When travel benefits are reimbursed rather than provided in-kind, payments from the nonfederal source will be by check or similar instrument made payable to the employee’s organization. Any such payment to the

organization received by the employee should be submitted with his or her travel voucher as soon as practicable. In-kind travel benefits that were furnished by an NFE to ensure that appropriate deductions are made in the travel, per diem, and other allowances payable by the United States should be excluded in the travel voucher.

Travel-approving authorities designated to accept travel benefits from NFEs shall submit a report to the DoD component designated agency ethics official (DAEO), the alternate DAEO, or designee semiannually (on April 30 and October 31) to accommodate the required reporting to the Office of Government Ethics (on May 31 and November 30 of each year). Within the US Army Medical Command, reports are consolidated and forwarded by the MEDCOM Office of the Staff Judge Advocate.

ACCEPTANCE OF TRAVEL BENEFITS INCIDENTAL TO TRAINING OR IN CONJUNCTION WITH PRESENTATION OF AN AWARD

In accordance with 5 USC §4111 and JER, paragraph 4-102,^{1(p47)} military employees can accept contributions, awards, travel benefits, and other payments from NFEs incidental to training in nongovernment facilities. Benefits can be accepted directly from NFEs only when all of the following conditions are met:

1. The source is a tax-exempt organization described by 26 USC §501(c)(3) or a state or local government (see 5 CFR 410, Subpart G).
2. The contribution, award, or payment of travel benefits is incidental to training in nonfederal government facilities or attendance at a meeting.
3. An appropriate deduction is made from any payment by the federal government to the employee for his or her official travel entitlement.
4. The contribution, award, or payment is not a reward for services to the NFE.
5. Acceptance of the contribution, award, or payment would not reflect unfavorably on the employee’s ability to perform his or her duties in a fair and objective manner, nor would it otherwise compromise the integrity of any federal government action.
6. The travel approving authority authorizes the acceptance of the contribution, award, or payment in writing.

Gifts of Travel Benefits from Nonfederal Sources to Military and Civilian Government Employees

In accordance with 5 CFR 2635.204(d), cash prizes may be accepted by military employees if they are part of a bona fide award, or incident to a bona fide award, that is given for meritorious public service or achievement by an individual or organization that does not have interests which may be substantially affected by the performance or nonperformance of the employee's official duties. Examples of such an award include the Nobel Prize for Medicine and the Russell and Burch Award presented by the Humane Society of the United States.

Employees who receive an award or prize may also accept travel benefits, meals, and entertainment given to them and to members of their families at the event at which the presentation of the award takes place. If the value of these benefits, combined with the value of the prize, is more than \$200, a written determination is required from an ethics counselor that the award is part of an established plan of recognition made on a regular basis pursuant to written standards.

Finally, when more than one organization participates in making a single contribution, award, or travel payment, only the organization that actually selects the recipient and administers the funds from which the contribution, award, or travel payment will be made will be considered as the source of the travel benefits. Individuals who are required to file financial disclosure statements must report acceptance of such travel benefits on their financial disclosure statements if the fair market value of those benefits meet or exceed the reportable amount.

PROCEDURES AND RESPONSIBILITIES OF THE TRAVEL-APPROVING AUTHORITY, THE TRAVELER, AND THE ETHICS COUNSELOR

Generally, the travel-approving authority shall:

- Approve or disapprove acceptance of travel benefits in-kind or payments of travel expenses from nonfederal sources.
- Acquire the concurrence of the ethics counselor when approving travel benefits in accordance with the conflict of interest analysis required by 41 CFR 304-1.5.
- Prepare and submit a report to the DoD component designated agency ethics official or designee (normally the servicing ethics counselor), reporting all travel benefits over \$335 accepted in

accordance with the authority granted under 31 USC §1353.

- Prepare and submit a report to the DoD component DAEO or designee (normally the servicing ethics counselor), within 30 days after completion of travel for which travel benefits have been paid by nonfederal sources under 5 USC §4111.

Generally, ethics counselors will:

- Prepare and submit semiannual reports of payments under 31 USC §1353 (due May 31 and November 30 of each year).
- Retain reports from the travel-approving authority under 5 USC §4111 for 2 years.
- Provide written concurrence or nonconcurrence for the approval of travel benefits, in accordance with the conflict of interest analysis required by 41 CFR 304-1.5.

Generally, each military employee shall prepare and submit a report (sample report provided on page 67) to the travel-approving authority reporting all travel benefits received that totaled \$335 or more, in accordance with the provisions of 31 USC §1353. The report should provide the following information, be signed by both the traveler and the travel-approving authority, and forwarded to the servicing legal office:

1. Name of the reporting organization.
2. List of each event, (meeting, or similar function) for which the organization accepts payment of more than \$335 (for a member and spouse together, or for either the member or the spouse separately), including sponsor of the event, location of the event, date(s) of the event, and nature of the event.
3. Name of each member for whom such payment was accepted in connection with the event, including the member's government position and member's travel date(s) in connection with attendance at the event.
4. Name of the accompanying spouse, if applicable, for whom payment was accepted in connection with the event, including the name of the member accompanied by the spouse, member's government position, and spouse's travel date(s) in connection with attendance at the event.

5. Identity of any nonfederal source from which payment was accepted in connection with the event.
6. Itemization of the benefits accepted by the organization in connection with attendance at the event, including a description of the benefit, provided that benefits accepted as a part of a conference or training fee need not be reported separately; method of payment (payment in-kind, or by check or similar instrument); individual for whom payment was accepted (member or spouse); the name of the nonfederal source that provided the benefit(s); and the amount of payment.
7. Total value of the payments accepted for the member and/or spouse in connection with the event, indicating the total amount of payments provided by check or similar instrument and the total value of payments provided in-kind.
8. Provide all necessary information to the travel-approving authority for a semiannual report to the DoD Component DAEO.

9. Turn in any merchandise or other benefits as required under the JER.

REFERENCES

1. *Department of Defense 5500.7-R: Joint Ethics Regulation*. Washington, DC: US Dept of Defense; March 3, 2006. Available at: http://www.dod.mil/dodgc/defense_ethics/ethics_regulation/jer1-6.doc. Accessed January 14, 2010.
 2. *Department of Defense Directive 1005.13: Gifts and Decorations from Foreign Governments*. Washington, DC: US Dept of Defense; December 6, 2002. Available at: <http://www.dtic.mil/whs/directives/corres/html/100513.htm>. Accessed January 14, 2010.
 3. 41 CFR 304-5.3.
-

AUTHOR

MAJ Topinka is Deputy Staff Judge Advocate, US Army Medical Command, Fort Sam Houston, Texas.



Gifts of Travel Benefits from Nonfederal Sources to Military and Civilian Government Employees

MEMORANDUM FOR THE RECORD

SUBJECT: Approval of Acceptance of Travel Benefits Pursuant to 31 USC §1353

1. Travel benefits have been offered by ___[name of nonfederal entity]___ to ___[name of Army personnel who will receive the travel benefit]___ to permit him/her to ___[insert the reason the person will be traveling]___. This event will occur on ___[insert dates]___. The Army employee will ___[explain further what the army employee will be doing, if necessary. Attach program brochure or the offer letter from the nonfederal entity, if available.]___.
2. The following travel and related expenses have been offered to be provided in-kind to the Department of the Army:
 - Round-trip air fare [approximate value]
 - Rental car [estimated cost]
 - Lodging [approximate hotel rate]
 - Meals [identify the meals to be provided]
 - Registration fee [full value]
3. I have reviewed the offer of travel benefits, taking into account such factors as the source of the gift, the amount of the gift, to whom it is offered, whether there are any matters pending before the Army concerning the nonfederal entity offering the travel benefits and whether the proposed recipient of the travel benefits makes any decisions pertaining to the nonfederal entity.
4. I hereby determine that the acceptance of these travel benefits would / would not [select one] cause a reasonable person with knowledge of all the relevant facts to question the integrity of the Army's programs or operations and approve / disapprove [select one] acceptance of the above-described travel benefits.
5. This approval has been coordinated with the Ethics Counselor and written approval has been obtained as evidenced by the concurrence block below OR the attached written opinion [select one]. If the travel benefits received exceed \$335, the traveler will file a report of travel benefits accepted to their Ethics Counselor within 15 days of completion of the travel.
6. A copy of this memorandum and attachments shall be retained by the recipient of the travel benefits and his/her ethics counselor.

Signature Block and title of travel approval authority

Ethics Counselor Coordination

Concur _____ Nonconcur _____

Date: _____

Sample of memorandum form to document record of the nonfederal entity offer to provide travel benefits to Department of the Army personnel, and concurrence or nonconcurrence by the ethics counselor.

THE ARMY MEDICAL DEPARTMENT JOURNAL

REPORT OF SPONSOR PAYMENT OF TRAVEL AND RELATED EXPENSES
ACCEPTED FROM NONFEDERAL SOURCES

(31 USC, §1353)

Employee's Name: _____

Command/Organization: _____

Employee's Position: _____

Spouse's Name (if applicable): _____

Event (for which more than \$335 in travel and related expenses were donated)

Nature/Title of Event: _____

Sponsor: _____

Location: _____

Dates: From _____ To: _____

Type Of Donation

Donating Organization: _____

Total Amount: _____

Amount of Payments-in-Kind: For Employee: _____ For Spouse _____
(Prepaid: conference fees, hotel costs, airline tickets, meals, etc.)

Amount of Payment by Check: For Employee: _____ For Spouse _____
(Check must be made to "Department of the Army" and submitted to your travel office)

Itemized Expenses

Hotel: _____

Airline: _____

Meals: _____

Other: _____

Your Certification

"I certify that the statement on this report are true, complete, and correct to the best of my knowledge."

Signature Date

Submit Report To Your Ethics Counselor Below Within 15 Days Of Travel

Sample of report to the travel-approving authority reporting all travel benefits received that totaled \$335 or more, in accordance with the provisions of 31 USC §1353.

Off-Duty Employment of Department of Defense Health Care Providers

CPT Holly Bryant, JAG, USA

INTRODUCTION

Department of Defense (DoD) policy limits the outside employment activities of DoD healthcare providers. This article provides an overview of US Army Medical Command (MEDCOM) regulations and policies affecting off-duty employment (ODE) as well as Army regulations relevant to special categories of off-duty work. It also highlights where joint ethics regulation standards intersect with ODE issues.

GENERAL RULES

The promulgating authority is the Assistant Secretary for Health Affairs. *DoD Health Affairs Policy 96-050*¹ sets forth the DoD-wide rules governing off-duty employment by healthcare providers. The DoD policy is implemented within the Army Medical Command by *MEDCOM Regulation 600-3*.² Subordinate commands have further implemented procedures for filing and processing ODE applications.

The ODE rules ensure all military and civilian healthcare providers' "time, talents, and attention" are devoted first and foremost to their military healthcare duties as provided in paragraph 6b of *MEDCOM Regulation 600-3*.^{2(pp2-3)} The DoD and MEDCOM policies tolerate no interference from voluntary outside employment obligations on the mission of providing round-the-clock health care to the Soldier and other beneficiaries.

All ODE must be approved by the healthcare provider's commander in writing before the healthcare provider is authorized to begin the work. Timely processing of requests will help to ensure providers do not circumvent the approval process because of missed outside professional opportunities. In practice, personnel do knowingly fail to seek approval for covered activities; paragraph 6a of *MEDCOM Regulation 600-3*.^{2(p2)} states that noncompliance with the process is grounds for punishment under the

Uniform Code of Military Justice,* as well as grounds for other authorized administrative actions. The clinical quality management program and credentialing processes described in *Army Regulation 40-68*⁴ are examples of such otherwise authorized administrative actions.

The purpose paragraph of *MEDCOM Regulation 600-3*^{2(p1)} uses the term "off-duty commitments" and defines it as encompassing professional work and nonprofessional (nonmedical) work, including self-employment, and healthcare work done on a volunteer basis. In this paper, "ODE" should be understood to encompass all of these activities.

Healthcare providers subject to *MEDCOM Regulation 600-3* include all persons delivering direct patient care as designated by the Assistant Secretary of Defense. The list of professions includes: physicians, dentists, registered nurses, practical nurses, physical therapists, podiatrists, optometrists, clinical dieticians, social workers, clinical pharmacists, clinical psychologists, occupational therapists, audiologists, speech pathologists, and physician assistants.^{2(pp1-2)}

LIMITATIONS ON OFF-DUTY EMPLOYMENT

Hours. Because military duties cannot be impaired by ODE, the regulation restricts work hours and travel time between the duty location and the ODE location. The regulation mandates the provider allow a 6-hour rest period following ODE before resuming regular duties (a rest period before ODE is not required by regulation, but providers should exercise appropriate professional judgment about whether rest is needed). The regulation directs commands to develop local

*The Uniform Code of Military Justice (UCMJ), a federal law,³ is the judicial code which pertains to members of the United States military. Under the UCMJ, military personnel can be charged, tried, and convicted of a range of crimes, including both common-law crimes (eg, arson) and military-specific crimes (eg, desertion).

procedures to implement the program; some localities require that the government supervisor endorse the provider's application and comment on the impact of ODE on care in the clinical setting (based on appointment demand, waiting times, and current staffing). This is a helpful addition to the application packet in a medical treatment facility (MTF) or community hospital, but may not be applicable to all practice settings.

Trainees. Officer trainees in graduate training programs are prohibited from engaging in off-duty employment. At MTFs, this will include interns and residents.

Status. Off duty employment cannot be performed in a permissive temporary duty status, or while on pass or compensatory time for overtime previously worked; regular leave may be used if this does not adversely impact the military mission. The ODE cannot incur any expense to the government, including use of military equipment or supplies.

Reports. A monthly report is required from each person performing ODE; the report of hours worked must be signed by the civilian employer. The commander of each provider engaged in ODE must submit an annual report to MEDCOM summarizing the ODE hours worked by each of those providers.

PROCEDURES

Samples of 2 types of applications are provided in the appendices of *MEDCOM Regulation 600-3*,^{2(pp8-14)} one for professional ODE (Appendix A) and one for nonprofessional ODE (Appendix B). There is also a sample letter of acknowledgement for the proposed ODE employer to sign (Appendix E). The letter of acknowledgement, which should be provided in the ODE application packet, memorializes the employer's understanding that:

- The provider cannot accept responsibility for ongoing care of patients.
- The provider must respond to the government employer's alerts and must accordingly leave the ODE worksite if called.
- The employer cannot bill TRICARE,* medicare, medicaid, or collect payment from patients directly

*TRICARE is DoD's health care program for members of the uniformed services, their families, and their survivors. Information available at <http://www.tricare.mil>.

when the patients are DoD beneficiaries receiving care from a DoD healthcare provider.

- The ODE will not involve expense to the government.
- The hours will be limited to 16 per week unless an exception has been granted in advance.
- The employer will sign monthly reports of hours worked.
- The employer will provide information to the commander about the ODE upon request.

An exception to the policy forbidding ODE employers from billing DoD beneficiaries exists for dental care given to dependents, Retirees, and Retiree family members. Because these persons are not entitled to free dental care at the Dental Activity, there is no conflict for DoD providers to charge fees for care in their off-duty capacity.⁵

All personnel are responsible for obtaining the appropriate licenses and insurance to practice in the private sector. Off-duty employment is not covered under the federal Tort Claims Act⁶ or the Gonzales Act.⁷ Personnel who will prescribe drugs must abide by the federal Controlled Substances Act⁸ and Drug Enforcement Agency rules, and they must register and pay taxes, as do all nonfederal providers.

EACH OFF-DUTY EMPLOYMENT ARRANGEMENT MUST BE APPROVED SEPARATELY

The requirement to obtain advance written approval applies whether or not any of the covered activities are undertaken on a voluntary basis or on leave, including transition leave. ODE offers a seamless transition to post government employment and is a popular means of transitioning; the conflict of interest analysis required by the ODE regulation should mirror the analysis and counseling ethics counselors give all personnel transitioning out of government service. The same conflict of interest concerns, including potential for the appearance of conflicts, arise in ODE as in post government employment.

TYPES OF OFF-DUTY EMPLOYMENT; PRIVATE MEDICAL PRACTICE; LOCUM TENENS

*MEDCOM Regulation 600-3*² specifically forbids covered personnel from engaging in solo medical practice or assuming continuing care for a patient or

Off-Duty Employment of Department of Defense Health Care Providers

patients, due to the potential for conflict with official duties. Covered personnel should be working ODE in a team setting in which other practitioners can provide follow-up care to patients. Some medical specialty areas lend themselves better to a variety of practice arrangements that are closer to the line. For example, it may be feasible for a healthcare provider to enter ODE practice with a partner during transition leave for the purpose of providing surgical or anesthesia care, or performing radiology or pathology work, because the partner and the patients' primary care doctors provide the necessary follow-up care. Specialty areas with high patient contact like internal medicine, oncology or family practice probably require an ODE setting with more providers to ensure follow-up care is covered. Providers should make clear in their application how their proposed ODE meets the requirements if it appears problematic.

WRITING, TEACHING, SPEAKING, AND LECTURING

Although the MTF commander is the approval authority for these ODE activities, practitioners must be mindful of the potential public affairs (PA), operational security (OPSEC), and intellectual property (IP) implications of their public speaking and writing activities.

Speaking and writing will not be considered ODE if they are uncompensated, related directly to official duties, and performed on official time, whether on offsite temporary duty status or not. The PA, OPSEC, and IP concerns do continue to pertain to official publication, teaching, and speaking.

Prior to publicly releasing any official medical information in any form, providers must obtain review from the PA officer, designated OPSEC officer, and the commander's designated medical reviewer.

SERVING AS A MEDICAL CONSULTANT FOR REMUNERATION

Practitioners who are board-certified in a specialty or who are designated consultants to The Surgeon General may consult with civilian practitioners for remuneration if they have advance written approval from the Commander and the patient in question is not a DoD healthcare beneficiary. If the patient is a beneficiary, the consultation can be done, but without the remuneration.

EXPERT TESTIMONY

Paragraph 7-10 of *Army Regulation 27-40* prohibits giving testimony as a medical expert witness in private litigation.⁹ *MEDCOM Regulation 600-3* further defines medical expert witness work to include work as a medico-legal consultant for a law firm, whether or not in-court testimony is to be involved.^{2(p6)} Commanders are not authorized to approve such work or testimony. Rather, paragraph 7-10b of *Army Regulation 27-40* states:

...the Litigation Division may grant special written authorization for present or former DA [Department of the Army] personnel to testify as expert or opinion witnesses at no expense to the United States.⁹

If an ODE question arises regarding expert or opinion testimony, legal advisors should advise their commanders of this limit to their authority and facilitate coordination with the Office of the Judge Advocate General, Litigation Division.

PROVIDING VOLUNTEER HEALTHCARE SERVICES

Healthcare providers may participate in their personal capacity in medical and humanitarian missions with private groups of all kinds, including those providing care to institutionalized persons. Legal representatives of the MTF must review these ODE proposals for conflicts of interest. *MEDCOM Regulation 600-3* requires the benefiting institution to obtain a letter from the provider's commander stating that

the individual is performing charitable work as a private citizen and that the Government assumes no responsibility for the individual's actions.^{2(p6)}

OUTSIDE EMPLOYMENT OF A NONPROFESSIONAL NATURE, INCLUDING SELF-EMPLOYMENT

This category includes sales work of all kinds, including the following list given in the purpose paragraph of *MEDCOM Regulation 600-3*:

...insurance, stocks, mutual funds, cosmetics, household supplies, vitamins, and other consumer goods and services, whether commercially manufactured or handcrafted.^{2(p1)}

Again, these must be approved in advance; additionally, the rules prohibiting the use of government resources for personal business enterprises and solicitation in the federal workplace apply to these activities.

CONCLUSION

The rules governing ODE are designed to make a blanket prohibition on ODE unnecessary. They are technical, and providers often resent both the rules and the process of getting an application approved. An effective local policy and institutional effort to minimize the time to process these applications can make the rules painless to live with, ensure the transparency of providers' extracurricular activities, protect providers from unintended consequences, and ensure the military healthcare mission is fully supported by its human resources.

REFERENCES

1. *Department of Defense Health Affairs Policy 96-050: Policy for Off-Duty Employment by DoD Health Care Practitioners*. Washington, DC: US Dept of Defense; July 23, 1996.
2. *US Army Medical Command Regulation 600-3: Off-Duty Employment*. Fort Sam Houston, TX: US Army Medical Command; March 21, 2008.

3. 64 Stat. 109, 10 USC, chap 47.
4. *Army Regulation 40-68: Clinical Quality Management*. Washington, DC: US Dept of the Army; February 26, 2004.
5. *Department of Defense Health Affairs Policy 97-019: Off-Duty Employment by DoD Dental Providers*. Washington, DC: US Dept of Defense; July 23, 1996.
6. 28 USC §§2671-2680.
7. 10 USC §1089.
8. 21 USC §801 et seq.
9. *Army Regulation 27-40: Litigation*. Washington, DC: US Dept of the Army; September 19, 1994:16.

AUTHOR

CPT Bryant is a Recruiting Officer, Judge Advocate Recruiting Office, Rosslyn, Virginia.



Witnesses: The Rules for Army Health Care Providers

CPT Ean P. White, JAG, USA

BACKGROUND

Attorneys frequently want Department of the Army healthcare providers (HCPs) to serve as witnesses in litigation, which is defined as

...all pretrial, trial, and post trial stages of all existing or reasonably anticipated judicial or administrative actions, hearings, investigations, or similar proceedings before civilian courts, commissions, boards...or other tribunals, foreign and domestic.^{1(p37)}

This broad definition also includes

...responses to discovery requests, depositions, and other pretrial proceedings, as well as responses to formal or informal requests by attorneys or others in situations involving litigation.^{1(p37)}

TYPES OF LITIGATION

Litigation in Which the United States Has an Interest

This category encompasses cases in which the United States is either named as a party or has an official interest in the outcome of the litigation. Examples include medical malpractice complaints brought under the Federal Tort Claims Act² and suits by the government pursuant to the Medical Care Recovery Act.³

Private Litigation

Private litigation is that litigation in which the government is not a party and has no official interest in the outcome. Examples include personal injury cases in which the Army provided medical care, non-Department of Defense civilian medical malpractice cases, divorce proceedings, child abuse hearings, and competency hearings of retirees or dependents.

TYPES OF REQUESTED TESTIMONY

There are 2 types of requested testimony: expert testimony, when a litigant seeks a professional opinion, hypothetical responses, and/or prognosis from the HCP; and factual testimony, when a litigant seeks facts from an Army HCP concerning medical care such as treatment or observations provided to one of the parties.

APPEARANCE AS A WITNESS

Generally, Department of the Army personnel may not appear as witnesses in any litigation absent proper authorization. Such authorization will usually be granted if certain conditions are met.

Litigation in Which the United States Has an Interest

When the United States is a party or has an interest in the litigation, there is only one restriction on the testimony of Army HCPs: they may not provide opinion or expert testimony for a party whose interests are adverse to those of the United States. All requests for Army HCPs to serve as expert or opinion witnesses for the United States are referred to the Litigation Division, Office of the Judge Advocate General (Litigation Division), unless the request involves a matter that has been delegated to a Staff Judge Advocate (SJA) or legal advisor. All requests for interviews or subpoenas for the testimony of Army HCPs are referred to the SJA or legal advisor serving the provider's medical treatment facility.

Travel arrangements for witnesses for the United States are normally made by the Department of Justice through the Litigation Division, which issues instructions for the witness travel, including a fund citation, to the appropriate commander. An SJA or legal advisor may make arrangements for the local travel of Army HCPs requested by US Attorneys, or by attorneys representing the government's interests in actions brought under the Medical Care Recovery Act,³ provided that the HCP is stationed at an installation in the same judicial district or not more than 100 miles from the place where testifying.

Private Litigation

Expert or Opinion Testimony. Army HCPs may not provide expert or opinion testimony in private litigation. That restriction applies even if the HCP is to testify without compensation. Additionally, although certain exceptions apply to other Department of the Army personnel, those exceptions apparently do not apply to HCPs. The Chief of the Litigation Division should be contacted on a case-by-case basis. If a court or other appropriate authority orders an Army HCP to provide expert or opinion testimony, the witness must

immediately notify the Litigation Division. The Litigation Division will determine whether to challenge the subpoena or court order and will direct the witness to either testify or to respectfully decline to comply.⁴

Factual Testimony. Army HCPs may provide factual testimony in private litigation concerning patients they have treated, investigations they have made, laboratory tests they have conducted, or other actions they have taken in the regular course of their duties. Such testimony must be approved by the SJA or medical treatment facility (MTF) legal advisor and the HCP's supervisor. In such cases, the HCP's testimony must be limited to factual matters and it may not extend to hypothetical questions or to a prognosis.

Legal Representative. Frequently at depositions or at trial, counsel ask treating physicians to give expert or opinion testimony despite the regulatory prohibitions against such testimony. Consequently, a Judge Advocate or Army civilian attorney "should be present during any interview or testimony to act as legal representative of the Army."^{1 (p16)} If a question in an interview or deposition seeks expert or opinion testimony, the legal representative will advise the Army HCP not to answer the question. In the case of court testimony, the legal representative should advise the judge that Department of Defense directives and Army regulations prohibit the witness from answering the question without the approval of the Department of the Army.

OTHER MATTERS

Moonlighting

If, because of off-duty employment, an Army HCP is required to participate in private litigation as either a defendant or as a treating physician, any testimony provided must be limited to factual matters. This limitation ensures that government imprimatur is not given to the HCP's testimony. Under no circumstances are Army medical personnel allowed to "moonlight" as expert witnesses. This includes off-duty employment as a medical/legal consultant for a law firm or attorney, even if actual in-court testimony is neither required nor desired by the firm or attorney.

Medical Records

Army HCPs who are subpoenaed to testify at a deposition or trial frequently receive a subpoena duces tecum to produce pertinent medical records. Army medical records are the property of the US government⁵

and the MTF commander is the official medical records custodian at his or her facility. The chief of the MTF's Patient Administration Division (PAD) acts for the MTF commander in matters pertaining to medical records. Consequently, requests for medical records should be made to the PAD where the request will be processed in accordance with applicable rules and regulations. Stricter rules govern the release of alcohol abuse or drug abuse treatment records.

Quality Assurance Information

HCP may be asked to testify regarding quality assurance information in situations which do not qualify as an exception to the prohibition against disclosure of quality assurance information outlined in 10 USC §1102. For example, an HCP is asked to be a witness in a fact-finding meeting in conjunction with an equal opportunity complaint lodged by another HCP. The equal opportunity complainant alleges the quality assurance process by the MTF was based upon racial discrimination and compels the HCP to testify regarding details of the process. The HCP is not permitted to testify or release quality assurance information in any form to the equal opportunity officer. Another example of an equal opportunity request for impermissible disclosure would be an allegation by the complainant that the quality assurance process was instituted by the MTF in retaliation for previous complaints against the MTF by the complainant. All requests for testimony or other disclosure of quality assurance information must be evaluated on a case-by-case basis by the MTF commander with the assistance of legal counsel, following notification to the US Army Medical Command Office of the Staff Judge Advocate.

REFERENCES

1. *Army Regulation 27-40: Litigation*. Washington, DC: US Dept of the Army; September 19, 1994.
2. 28 USC §2671-2680 and 1346(b).
3. 28 USC §2651.
4. *US ex rel Touhy v Ragen*, 340 US 462 (1951).
5. *Army Regulation 40-66: Medical Record Administration and Healthcare Documentation*. Washington, DC: US Dept of the Army; June 17, 2008.

AUTHOR

CPT White is Assistant Staff Judge Advocate, US Army Medical Command, Fort Sam Houston, Texas.

The Judge Advocate General's Corps of the United States Army

The Judge Advocate General's Corps of the United States Army is composed of Army officers who are lawyers and who provide legal services to the Army at all levels of command. The Judge Advocate General's Legal Service includes judge advocates, warrant officers, paralegal noncommissioned officers and junior enlisted personnel, and civilian employees. The Judge Advocate General is a lieutenant general. All military officers are appointed by the US President subject to the advice and consent of the Senate, but the Judge Advocate General is one of the few positions in the Army explicitly provided for by law in Title 10 of the United States Code and which requires a distinct appointment.

THE JUDGE ADVOCATE GENERAL

General George Washington founded the US Army JAG Corps on July 29, 1775, with the appointment of William Tudor as the Judge Advocate General. The Army Judge Advocate General's Corps is the oldest of the judge advocate communities in the US armed forces, as well as the oldest "law firm" in the United States. The Judge Advocate General serves a term of 4 years. LTG Dana K. Chipman, appointed in October 2009, is the 38th Judge Advocate General of the Army.

MISSION

Judge advocates serve in the position of Staff Judge Advocate on the special and personal staff of general officers in command who are general court-martial convening authorities (the authority to convene a general court-martial). Staff Judge Advocates advise commanders on the full range of legal matters encountered in government legal practice and provide advice on courts-martial as required by the Uniform Code of Military Justice. Subordinate judge advocates prosecute courts-martial, and others, assigned to the independent US Army Trial Defense Service and US Army Trial Judiciary, serve as defense counsel and judges. The almost 2,000 full-time judge advocates and civilian attorneys who serve The Judge Advocate General's Corps comprise the largest group of attorneys who serve the US Army. Several hundred other attorneys practice under the Chief Counsel of the United States Army Corps of Engineers and the Command Counsel of the United States Army Materiel Command.

Judge advocates are deployed throughout the United States and around the world, including Japan, South Korea, Germany, Kosovo, Iraq, Afghanistan, Kuwait, and Qatar. They provide legal assistance to soldiers, adjudicate claims against the Army, advise commands on targeting decisions and other aspects of operational law, and assist the command in administering military justice by preparing nonjudicial punishment actions, administrative separation actions, and trying criminal cases at court-martial.

In addition to the active component judge advocates, there are approximately 5,000 attorneys who serve in the US Army Reserve and the Army National Guard. Several hundred Reserve and National Guard attorneys have left their civilian practices to serve in support of Operations Iraqi Freedom and Enduring Freedom.

LEGAL CENTER AND SCHOOL

The Judge Advocate General's School began in World War II at the University of Michigan to train new judge advocates as the Judge Advocate General's Department rapidly expanded. It was disestablished for a short time after the war. It was then reestablished at Fort Myer in Arlington, Virginia, but, after a short stay, was relocated to the University of Virginia in Charlottesville in 1951. The Judge Advocate General's Legal Center and School adjoins, but is distinct from, the University of Virginia School of Law. The Commandant of the Judge Advocate General's School is authorized by Congress to award a Master of Laws degree. The school is the only federal institution to have American Bar Association accreditation as an America's law schools. Judge Advocates from all 5 armed forces of the United States and international students attend the annual Judge Advocate Officer Graduate Course in which the Master's degree is awarded. The Legal Center and School also trains the Army's new judge advocates, provides continuing legal education for judge advocates and lawyers from throughout the United States government, and trains the Army's paralegal noncommissioned officers and court reporters. The School trains those officers appointed military judges, irrespective of service.

INSIGNIA

The branch insignia consists of a gold pen crossed above a gold sword, superimposed over a laurel wreath. The pen signifies the recording of testimony, the sword represents the military character of the JAG Corps, and the wreath indicates honor. The insignia was created in May 1890 in silver and changed to gold in 1899.

THE UNITED STATES ARMY MEDICAL DEPARTMENT REGIMENT

The US Army Medical Department was formed on July 27, 1775, when the Continental Congress authorized a Medical Service for an army of 20,000 men. It created the Hospital Department and named Dr Benjamin Church of Boston as Director General and Chief Physician. On 14 April, 1818 the Congress passed an Act which reorganized the staff departments of the Army. The Act provided for a Medical Department to be headed by a Surgeon General. Dr Joseph Lovell, appointed Surgeon General of the United States Army in April 1818, was the first to hold this position in the new organization. The passage of this law marks the beginning of the modern Medical Department of the United States Army.

Throughout its early history, the size and mission of the US Army Medical Department would wax and wane in response to military events around the world. There was, however, no formal regimental organization until World War I. Then, in the late 1950s, the brigade replaced the regiment as a tactical unit. In the reorganization that followed, some Army units lost their identity, their lineage, their history. This loss did not go unnoticed. The US Army Regimental System was created in 1981 to provide soldiers with continuous identification with a single regiment. Department of the Army Regulation 600-82, The US Army Regimental System, states the mission of the regiment is to enhance combat effectiveness through a framework that provides the opportunity for affiliation, develops loyalty and commitment, fosters a sense of belonging, improves unit esprit, and institutionalizes the war-fighting ethos.

The US Army Medical Department Regiment was activated on July 28, 1986, during ceremonies at Fort Sam Houston in San Antonio, Texas, the "Home of Army Medicine." Lieutenant General Quinn H. Becker, the US Army Surgeon General and AMEDD Regimental Commander, was the reviewing officer. He was joined by general officers of the US Army Reserves and the Army National Guard, representing the significant contributions and manpower of the reserve forces in the Total Army concept.

INSIGNIA

The AMEDD Regimental Distinctive Insignia was designed by the Institute of Heraldry and is one of the oldest crests in the Army today. The 20 stars on the crest correspond to the number of states in the Union between December 10, 1817, and December 3, 1818. The origin of the crest dates from the Act of April 14, 1818, by which the Medical Department of the Army was first organized.

The alternating red and white stripes on the left side of the shield are the 13 stripes of the American Flag. The green staff is the staff of Asclepius (according to Greek mythology, the first healer, the son of Apollo, the sun god); and green was a color associated with the Medical Corps during the last half of the 19th century. The phrase "To Conserve Fighting Strength" gives testimony to our mission as combat multipliers and guardians of our Nation's strength and peace.

INFORMATION

The Regimental web site (<http://ameddregiment.amedd.army.mil/default.asp>) is designed to provide you with useful information about the US Army Medical Department (AMEDD) Regiment. Through the web site, you can learn the history of the AMEDD Regiment, the symbolism behind our heraldic items, how to wear the Regimental Distinctive insignia, and various programs available to you and your unit.

The Office of the AMEDD Regiment is located in Aabel Hall, Building 2840, on Fort Sam Houston, Texas. The Regimental staff can provide further information pertaining to the history of the Army Medical Department and the AMEDD Regiment, and assist with any of the services described in the web page.

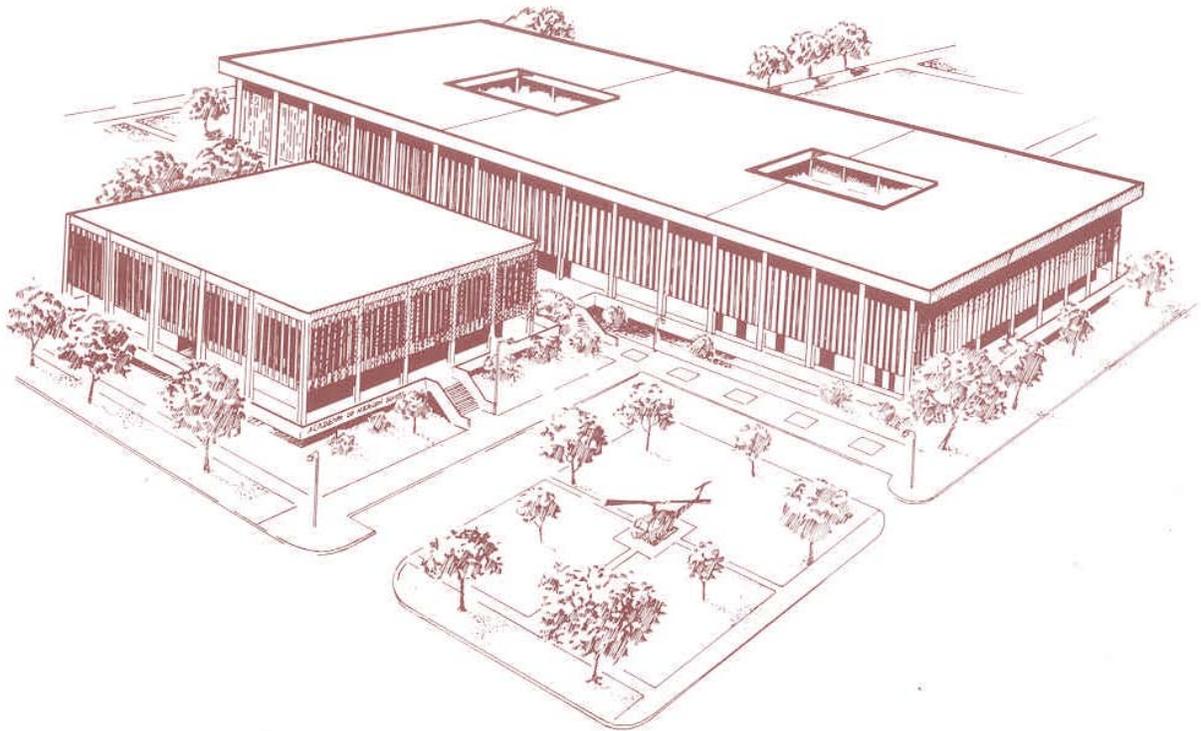
For additional information please contact the Army Medical Department Regimental Office at the following address:

Commander
US Army Medical Department Regiment
ATTN: MCCS-GAR
2250 Stanley Road
Fort Sam Houston, Texas 78234-6100

The telephone number is (210) 221-8455 or DSN 471-8455, fax 8697.

Internet: <http://ameddregiment.amedd.army.mil/>

Email: amedd.regiment@amedd.army.mil



The US Army Medical Department Center and School, Fort Sam Houston, Texas

SUBMISSION OF MANUSCRIPTS TO THE *ARMY MEDICAL DEPARTMENT JOURNAL*

The *United States Army Medical Department Journal* is published quarterly to expand knowledge of domestic and international military medical issues and technological advances; promote collaborative partnerships among the Services, components, Corps, and specialties; convey clinical and health service support information; and provide a professional, high quality, peer reviewed print medium to encourage dialogue concerning health care issues and initiatives.

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